

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and)	
BAYER HEALTHCARE LLC,)	
)	
Plaintiffs,)	
)	C. A. No. 05-349-GMS
v.)	
)	JURY TRIAL DEMANDED
BAXTER INTERNATIONAL INC. and)	
BAXTER HEALTHCARE CORPORATION,)	
)	
Defendants.)	
)	PUBLIC VERSION
_____)	
BAXTER HEALTHCARE CORPORATION,)	
)	
Counterclaimant,)	
)	
v.)	
)	
TALECRIS BIOTHERAPEUTICS, INC. and)	
BAYER HEALTHCARE LLC,)	
)	
Counterdefendants.)	

**DECLARATION OF ANNE M. ROGASKI IN SUPPORT OF DEFENDANT BAXTER
INTERNATIONAL INC. AND DEFENDANT/COUNTERCLAIMANT BAXTER
HEALTHCARE CORPORATION'S OPPOSITION TO PLAINTIFFS'
MOTIONS IN LIMINE**

OF COUNSEL:	Philip A. Rovner (#3215)
	POTTER ANDERSON & CORROON LLP
	Hercules Plaza
James G. Gilliland, Jr.	P.O. Box 951
Susan M. Spaeth	Wilmington, DE 19899-0951
Anne M. Rogaski	(302) 984-6000
TOWNSEND and TOWNSEND and	E-mail: provner@potteranderson.com
CREW LLP	
379 Lytton Avenue	<i>Attorneys for Defendant Baxter International</i>
Palo Alto, CA 94301	<i>Inc. and Defendant/Counterclaimant</i>
(650) 326-2400	<i>Baxter Healthcare Corporation</i>

Dated: May 7, 2007
Public Version: May 14, 2007

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Plaintiffs,

v.

BAXTER INTERNATIONAL INC. and
BAXTER HEALTHCARE CORPORATION,

Defendants.

Civil Action No. 05-349-GMS

Jury Trial Demanded

BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Counterdefendants.

PUBLIC VERSION

**DECLARATION OF ANNE M. ROGASKI IN SUPPORT OF DEFENDANT
BAXTER INTERNATIONAL INC. AND DEFENDANT/COUNTERCLAIMANT
BAXTER HEALTHCARE CORPORATION'S
OPPOSITION TO PLAINTIFFS' MOTIONS *IN LIMINE***

I, Anne M. Rogaski, declare:

1. I am a partner at the law firm of Townsend and Townsend and Crew LLP and one of the counsel of record for Defendant Baxter International Inc. and Defendant/Counterclaimant Baxter Healthcare Corporation (collectively "Baxter"). I make this declaration of my personal knowledge.

2. A true and correct copy of the Rule 26(a)(2)(B) Report of R. Bruce Den Uyl dated January 31, 2007 is attached hereto as Exhibit 1.

3. True and correct copies of pages 19-35, 122 and 142-147 of the highly

confidential deposition transcript from the February 27, 2007 deposition of R. Bruce Den Uyl are attached hereto as Exhibit 2.

4. True and correct copies of pages 14-15, 119, 146-147, 178-179 and 181-182 of the highly confidential deposition transcript from the August 22, 2006 deposition of Matt Fazio are attached hereto as Exhibit 3.

5. True and correct copies of pages 343-345 of the highly confidential deposition transcript from the September 29, 2006 deposition of Christophe Carnewal are attached hereto as Exhibit 4.

6. True and correct copies of pages 7-8 of the highly confidential deposition transcript from the October 6, 2006 deposition of Jennifer L. Bergstrom are attached hereto as Exhibit 5.

7. True and correct copies of the Expert Report of Christopher J. Bokhart and Exhibits 7.6 and 7.7 dated January 10, 2007 are attached hereto as Exhibit 6.

8. A true and correct copy of Plaintiffs' Rule 26(a)(1) Initial Disclosures dated April 7, 2006 is attached hereto as Exhibit 7.

9. A true and correct copy of Plaintiffs' supplemental initial disclosures dated July 14, 2006 is attached hereto as Exhibit 8.

10. True and correct copies of pages 74, 94 and 151-152 of the highly confidential deposition transcript from the February 22, 2007 deposition of Terrence Snape, Ph.D. are attached hereto as Exhibit 9.

11. A true and correct copy of the Expert Report of Thomas J. Kindt Concerning U.S. Patent No. 6,686,191 (without exhibits) dated January 10, 2007 is attached hereto as Exhibit 10.

12. True and correct copies of pages 142-143 and 145 of the highly confidential deposition transcript from the February 21, 2007 deposition of Christopher J. Bokhart are attached hereto as Exhibit 11.

13. A true and correct copy of *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 2006 WL 2724879 (D. Del. Sep. 20, 2006) is attached hereto as Exhibit 12.

14. A true and correct copy of the patent-in-suit, U.S. Patent No. 6,686,191 B1, is attached hereto as Exhibit 13.

15. A true and correct copy of *KSR Int'l Co. v. Teleflex Inc.*, 2007 U.S. LEXIS 4745 (2007) is attached hereto as Exhibit 14.

16. True and correct copies of pages 122-123 of the highly confidential deposition transcript from the February 28, 2007 deposition of Thomas J. Kindt, Ph.D. are attached hereto as Exhibit 15.

17. True and correct copies of pages 210, 216 and 242-244 of the highly confidential deposition transcript from the March 1, 2007 deposition of Thomas J. Kindt, Ph.D. are attached hereto as Exhibit 16.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct. Executed this 7th day of May, 2007 at Palo Alto, California.



Anne M. Rogaski

61043762 v1

Public Version: May 14, 2007

EXHIBIT 1

**THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY**

EXHIBIT 2

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EXHIBIT 3

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EXHIBIT 5

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EXHIBIT 6

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EXHIBIT 7

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC.,)
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 BAXTER HEALTHCARE CORPORATION,)
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 BAXTER HEALTHCARE CORPORATION)
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 Counterclaimant,)
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 TALECRIS BIOTHERAPEUTICS, INC., and)
 BAYER HEALTHCARE LLC,)
)
 Counterdefendants.)
)

C.A. No. 05-349-GMS

JURY TRIAL DEMANDED

PLAINTIFFS' RULE 26(a)(1) INITIAL DISCLOSURES

Pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure, plaintiff Talecris Biotherapeutics, Inc. ("Talecris") and counterdefendants Talecris and Bayer Healthcare LLC ("Bayer") make the following initial disclosures based on information reasonably available to them at this time. Continuing investigation and discovery may alter these disclosures. Talecris and Bayer reserve the right to supplement this initial disclosure to the extent that pertinent information is developed through further investigation.

By making these disclosures, Talecris and Bayer do not represent that they are identifying every document, tangible thing, or witness possibly relevant to this lawsuit. Nor do plaintiff and counterdefendants waive their right to object to production of any document or tangible thing

disclosed on the basis of any privilege, the work product doctrine, relevancy, undue burden, or any other valid objection. Rather, Talecris' and Bayer's disclosures represent a good faith effort to identify information they reasonably believe is discoverable and which may be used to support their claims or defenses (unless solely for impeachment) as required by Rule 26(a)(1).

Finally, Talecris' and Bayer's disclosures are made without waiving, in any way, (1) the right to object on the grounds of competency, privilege, relevancy and materiality, hearsay, or any other proper ground, to the use of any such information, for any purpose, in whole or in part, in any subsequent proceeding in this action or any other action; and (2) the right to object on any and all grounds, at any time, to any other discovery request or proceeding involving or relating to the subject matter of these disclosures.

All of the following disclosures are made subject to the above objections and qualifications.

A. INDIVIDUALS – Fed. R. Civ. P. 26(a)(1)(A)

Pursuant to Rule 26(a)(1)(A), Talecris and Bayer identify the individuals likely to have discoverable information that the disclosing party may use to support its claims or defenses, unless solely for impeachment. Talecris and Bayer do not give their consent for defendants (or their counsel or agents) to directly contact any current or former employee of Talecris or Bayer listed below.

1. Dr. William R. Alonso
Technology Department
Talecris Biotherapeutics, Inc.
8368 U.S. 70 West
Clayton, NC 27520
(919) 359-4346

Dr. Alonso is an employee of Talecris and is the named inventor on U.S. Patent No. 6,686,191 ("the '191 patent").

2. Dr. Clara Schreiner
Product Quality Management
Talecris Biotherapeutics
8368 US 70 West
Clayton, NC 27520
(919) 359-4404

Dr. Schreiner is an employee of Talecris. Dr. Schreiner may possess information about, *inter alia*, the measurement of anticomplement activity for the '191 patent.

3. Dr. Wolfgang Teschner

Upon information and belief, Dr. Teschner is an employee of Baxter Healthcare Corporation in Vienna, Austria. Dr. Teschner may possess information about, *inter alia*, the subject matter of his declaration, which is document D24 of the opposition to European Patent No. 0 764 447 ("the '447 opposition").

4. Dr. Brian Alexander Crowe

Upon information and belief, Dr. Crowe is an employee of Baxter Vaccine AG in Orth, Austria. Dr. Crowe may possess information about, *inter alia*, the subject matter of his declaration, which is document D18 of the '447 opposition.

5. Dr. Herwig Igel

Upon information and belief, Dr. Igel is an employee of Baxter Healthcare Corporation in Vienna, Austria. Dr. Igel may possess information about, *inter alia*, the subject matter of document D12 of the '447 opposition.

6. Dr. Harald Arno Butterweck

Upon information and belief, Dr. Butterweck is an employee of Baxter Healthcare Corporation in Vienna, Austria. Dr. Butterweck may possess information about, *inter alia*, the subject matter of document D24 of the '447 opposition.

7. Dr. Yendra Linnau

Upon information and belief, Dr. Linnau is an employee of Baxter Healthcare Corporation in Vienna, Austria. Dr. Linnau may possess information about, *inter alia*, the subject matter of document D24 of the '447 opposition.

8. Mr. Mag. Petra Axmann

Upon information and belief, Mr. Axmann is an employee of Baxter Healthcare Corporation of Vienna, Austria. Mr. Axmann may possess information about, *inter alia*, the subject matter of document D24 of the '447 opposition.

9. Ms. Birgit Umlauf

Upon information and belief, Ms. Umlauf is an employee of Baxter Healthcare Corporation in Vienna, Austria. Ms. Umlauf may possess information about, *inter alia*, the subject matter of document D24 of the '447 opposition.

10. Mr. Ing. Bernhard Kölbl

Upon information and belief, Mr. Kölbl is an employee of Baxter Healthcare Corporation in Vienna, Austria. Mr. Kölbl may possess information about, *inter alia*, the subject matter of document D24 of the '447 opposition.

B. DOCUMENTS – Fed. R. Civ. P. 26(a)(1)(B)

Pursuant to Rule 26(a)(1)(B), Talecris and Bayer set forth a description by category and location of all documents, data compilations, and tangible things that are in the possession, custody, or control of Talecris and that it may use to support its claims or defenses, unless solely for impeachment.

1. Copy of U.S. Patent Number 6,686,191 and its prosecution history. Location: publicly available.
2. Documents relating to conception and reduction to practice of the invention disclosed in U.S. Patent Number 6,686,191, unless subject to a claim of privilege. Location: in the possession of Talecris.
3. Copy of European Patent Number EP 0 764 447 and its prosecution history. Location: publicly available.

4. Documents relating to the inventions disclosed in European Patent Number EP 0 764 447, unless subject to a claim of privilege. Location: publicly available or in the possession of Talecris.

C. DAMAGES - Fed. R. Civ. P. 26(a)(1)(C)

The damages-related disclosures governed by Rule 26(a)(1)(C) cannot reasonably be made at this early stage, other than to incorporate by reference the damages disclosures enumerated in the prayer for relief set forth in the Amended Complaint.

D. INSURANCE - Fed. R. Civ. P. 26(a)(1)(D)

Plaintiffs are not aware of any insurance agreement under which any person carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in the action or to indemnify or reimburse for payments made to satisfy the judgment.

CONNOLLY BOVE LODGE & HUTZ LLP

By: 

Jeffrey B. Bove (#998)

Mary W. Bourke (#2356)

Mark E. Freeman (#4257)

Jaclyn M. Mason (#4737)

1007 North Orange Street

P.O. Box 2207

Wilmington, DE 19899-2207

(302) 658-9141

Bradford J. Badke, Esquire
Gabrielle Ciuffreda, Esquire
ROPES & GRAY LLP
1251 Avenue of the Americas
New York, NY 10020-1105

Attorneys for Bayer Healthcare LLC

*Attorneys for Talecris Biotherapeutics, Inc. and
and Bayer Healthcare LLC*

DATED: April 7, 2006

CERTIFICATE OF SERVICE

I, Jeffrey B. Bove, do hereby certify that a true and correct copy of the foregoing
PLAINTIFFS' RULE 26(a)(1) INITIAL DISCLOSURES were served on April 7, 2006 upon
the following counsel of record in the manner indicated:

<u>Via Hand Delivery and E-Mail</u> Philip A. Rovner, Esquire Potter Anderson & Corroon LLP Hercules Plaza P. O. Box 951 Wilmington, DE 19899 (302) 984-6140 provner@potteranderson.com	<u>Via Federal Express and E-Mail</u> Susan Spaeth, Esquire Townsend and Townsend and Crew LLP 379 Lytton Avenue Palo Alto, CA 94301-1431 (415) 576-0200 smspaeth@townsend.com
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Jeffrey B. Bove

EXHIBIT 8



CONNOLLY BOVE LODGE & HUTZ LLP
ATTORNEYS AT LAW

Jeffrey B. Bove
Partner

TEL (302) 888-6241
FAX: (302) 658-9072
EMAIL jbove@cblh.com
REPLY TO Wilmington Office

The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington DE 19899
TEL (302) 658 9141
FAX (302) 658 5614

1990 M Street, NW, Suite 800
Washington DC 20036
TEL (202) 331 7111
FAX (202) 293 6229

WEB www.cblh.com

July 14, 2006

VIA E-MAIL

Susan M. Spaeth, Esquire
Townsend and Townsend and Crew LLP
379 Lytton Avenue
Palo Alto, CA 94301-1431

**RE: Talecris Biotherapeutics, Inc. v. Baxter International, Inc.
and Baxter Healthcare Corp., C.A. No. 05-349-GMS**

Dear Susan,

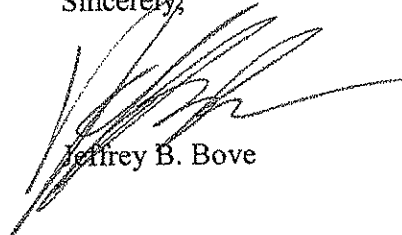
Further to our conversation today, in addition to individuals clearly identified in documents produced by Plaintiffs, Talecris and Bayer hereby supplement their identification of individuals as follows. As agreed, we intend to produce these individuals for deposition at our offices in Wilmington, and we continue to investigate their precise availability. The listed subject matter provided with each individual is not intended to be exhaustive or exclusive.

1. Dr. William Alonso, Deputy Director, Project Management Office
Talecris Biotherapeutics, Inc.
Research Triangle Park, NC
Subject matter: Experiments and research leading to, and the invention disclosed in, the '191 patent
2. Dr. George Baumbach, Senior Research Scientist
Talecris Biotherapeutics, Inc.
Research Triangle Park, NC
Subject matter: Supervision of Dr. Alonso and experiments and research relating to the '191 patent invention
3. Teresa Blackmon, Quality Control Biochemistry Supervisor
Talecris Biotherapeutics, Inc.
Clayton, NC
Subject matter: ACA assay
4. Mary Boguslaski, Esq.
Life Sciences Law PLLC
Chapel Hill, NC
Subject matter: Prosecution of the '191 patent

5. Tom Rains
Process Transfer Group Leader
Clayton, NC
Subject matter: Scale-up to manufacturing of product(s) produced by process claimed in '191 patent
6. Joan Robertson, Deputy Director, Regulatory Affairs
Talecris Biotherapeutics, Inc.
Subject matter: Regulatory filings (BLA, amendments to BLA, FDA correspondence)
7. Dr. Clara Schreiner, Quality Operations Manager, Product Quality Management
Talecris Biotherapeutics, Inc.
Clayton, NC
Subject matter: ACA assay
8. Susan Trukawinski, Senior Associate Process Development Scientist
Talecris Biotherapeutics, Inc.
Clayton, NC
Subject matter: Experiments and research relating to the invention of the '191 patent
9. Bill Zabel, Vice President, U.S. Commercial Operations
Talecris Biotherapeutics, Inc.
Research Triangle Park, NC
Subject matter: Sales and marketing

Mary Boguslaski is available for deposition during the week of August 14, 2006. Additionally, Dr. William Alonso and Dr. Clara Schreiner are available for deposition during the week of September 25, 2006. We reserve the right to further supplement this list.

Sincerely,



Jeffrey B. Bove

cc: Philip Rovner (via e-mail)
Bradford J. Badke (via e-mail)
Mary W. Bourke

EXHIBIT 9

**THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY**

EXHIBIT 10

**THIS EXHIBIT HAS BEEN
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EXHIBIT 11

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EXHIBIT 12

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Briefs and Other Related Documents

Power Integrations, Inc. v. Fairchild Semiconductor Intern., Inc. D.Del. 2006. Only the Westlaw citation is currently available.

United States District Court, D. Delaware.

POWER INTEGRATIONS, INC., a Delaware corporation, Plaintiff,

v.

FAIRCHILD SEMICONDUCTOR

INTERNATIONAL, INC., a Delaware corporation, and Fairchild Semiconductor Corporation, a Delaware corporation, Defendants.

No. CIVA 04-1371 JJF.

Sept. 20, 2006.

Frank E. Scherkenback, of Fish & Richardson P.C., Boston, Massachusetts, Howard G. Pollack, David J. Miclean, and Michael R. Headley, of Fish & Richardson P.C., Redwood City, California, William J. Marsden, Jr., and Sean P. Hayes, of Fish & Richardson, P.C., Wilmington, Delaware, for Plaintiff.

G. Hopkins Guy, III, Vickie L. Freeman, Bas de Blank, and Brian H. VanderZanden, of Orrick, Herrington & Sutcliffe LLP, Menlo Park, California, Steven J. Balick, John G. Day, and Tiffany Geyer Lydon, of Ashby & Geddes, Wilmington, Delaware, for Defendant.

MEMORANDUM OPINION

FARNAN, J.

*1 Pending before the Court are several motions filed by Plaintiff and Defendants. The Court will address each of the Motions in turn.

I. Defendants' Motion For Protective Order Regarding Deposition Of Michael C. Keeley, Rebuttal Expert Report On Damages And Continuation Of Damages Trial (D.I.309)

By their Motion, Defendants request a protective order (1) quashing Power Integration's notice of deposition of Michael C. Keeley, (2) setting reasonable dates for the submission of Dr. Keeley's rebuttal damages expert report and deposition, and (3) continuing the damages portion of the trial currently set for October 2, 2006. Defendants contend that Plaintiff has not

provided any discovery of its restated financial reports and that a revised damages report by Mr. Troxel contains new theories which Plaintiff should not be permitted to assert at this late date.

By e-mail to the Court dated August 21, 2006, the parties informed the Court that they reached an agreement concerning the deposition of Mr. Keeley. However, Defendants continue to press their motion to the extent that it seeks a continuation of the damages trial, particularly in light of the fact that Defendants still have not received Plaintiff's restated financial reports. Defendants also maintain that Mr. Troxel's second supplemental expert report on damages should be stricken.

The Court has addressed the continuation of the damages trial in this case in the context of a previous motion filed by Defendants and will not revisit that decision here. As for Plaintiff's financial reports, the Court addressed that subject at the Pretrial Conference and will also discuss it in the context of a pending motion in limine. Mr. Troxel's second supplemental expert report is the subject of a separate motion filed by Defendants, and therefore, will not be addressed by the Court in the context of this motion. Accordingly, the Court will deny as moot the Motion For Protective Order as it applies to Mr. Keeley's deposition and the deadlines for rebuttal expert reports, and deny the Motion For Protective Order in all remaining aspects.

II. MOTIONS IN LIMINE

A. Defendants' Motions In Limine (D.I.356-1)

1. Motion In Limine To Exclude Plaintiff's Claim For Damages Based On Defendants' Non-infringing Foreign Sales And Manufacture Of Products That Never Entered the U.S.

The Court has previously denied Defendants' Motion For Partial Summary Judgment Of Non-Infringement (Foreign Sales) and concludes that the instant motion more closely resembles a second summary judgment motion on that issue than a motion in limine. Accordingly, the Court will deny Defendants' Motion.

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2. Motion In Limine To Exclude Plaintiff's Claim For Evidence And Damages Based On Third Party Alleged U.S. Importation Of Accused Products

As with the previous Motion, the Court concludes that Defendant's second Motion In Limine is akin to a summary judgment motion. In this case, the jury will decide how many infringing sales and offers for sale took place in the United States based on the evidence submitted by the parties.^{FN1} Accordingly, the Court will deny Defendants' motion.

FN1. For both their first and second motions in limine, Defendants rely on a statement made by the Court in the context of addressing a motion in limine pertaining to the report of Mr. Lum. (D.I.334). The Court's statement was confined to the context of that dispute and was based solely on the excerpts of depositions provided by Defendants in connection with that motion. Thus, the Court did not intend for its statements to be construed as a commentary on the evidence as a whole or on the broader issue of alleged foreign sales and third party importation presented here.

3. Motion In Limine To Preclude Plaintiff From Relying On Decertified Financial Reports

*2 The Court has reviewed the parties' arguments with respect to this issue and concludes that Defendants have not demonstrated sufficient reason to preclude Plaintiff's from relying on the existing financial figures. To the extent that the existing figures may be changed at a later date, the Court can address the issue post-trial. Accordingly, the Court will deny Defendants' motion.

4. Motion In Limine To Exclude Evidence Of Alleged "Price Erosion"

The Court has reviewed the parties' arguments with respect to this issue and concludes that Defendants can address any deficiencies in Mr. Troxel's report through cross-examination. The Court is not persuaded that Plaintiff improperly concealed evidence from Mr. Troxel and disagrees with Defendants' assertion that products introduced by Plaintiff into the market prior to October 20, 2004, cannot provide a basis for damages, when the calculations relevant to those products are attributable to post October 20, 2004 sales. Accordingly, the Court

will deny Defendants' Motion.

5. Motion In Limine To Exclude All Evidence Of Damages Or Notice Prior To October 20, 2004

The Court has already addressed this issue in previous decisions and finds that further discussion of this issue is unwarranted. The Court will not expand its previous orders to embrace all pre-suit evidence and will not create a blanket presumption against the admission of such pre-suit evidence by requiring proffers that the evidence relates to infringement rather than damages. To the extent that Defendants have a concern about a particular piece of evidence, their concerns can be address at trial or during a side-bar conference. Accordingly, Defendants' motion will be denied.

6. Motion In Limine To Exclude Sales Reports And Other Documents As Unreliable

The Court has considered the parties' arguments concerning this issue and concludes that the reliability or unreliability of the documents identified by Defendants is a question reserved for the jury. As for Defendants' hearsay objections, the Court notes that Plaintiff contends that the documents fall within a number of exceptions to the hearsay rule. To the extent that Defendants maintain these objections and contend that these hearsay exceptions do not apply, the Court will consider such objections in the context of the trial so that the Court can fully evaluate the foundational evidence relevant to the exhibits. Accordingly, the Court will deny Defendants' motion.

7. Motion In Limine To Exclude Legal Opinions On Infringement

The Court has reviewed the parties' arguments with respect to this issue and concludes that Defendants are not entitled to relief. Although claim construction is a question of law, the ultimate question of infringement is a question of fact reserved for the jury. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 758 (Fed.Cir.1984). Thus, technical experts are permitted to give their opinions on the question of infringement. See Snellman v. Ricoh Co., 862 F.2d 282, 287 (Fed.Cir.1988), cert. denied, 491 U.S. 910 (1989). Accordingly, the Court will deny Defendants' Motion.

8. Motion In Limine To Exclude Evidence That Defendants Copied Plaintiff's Circuits Or Datasheets

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*3 The Court has reviewed the parties' arguments regarding this issue and concludes that the issue of copying presents questions for the jury. As for Defendants concerns regarding jury confusion, the Court concludes that such concerns are slight and likely to be fully ameliorated once the Court instructs the jury as to the applicable law. Accordingly, the Court concludes that Defendants will not be unduly prejudiced by this evidence, and therefore, the Court will deny Defendants' Motion.

9. Motion In Limine To Exclude Claims And Evidence Regarding Defendants' FSD210HD Product

Defendants contend that Plaintiff failed to identify the FSD210HD product as an accused device in any of its damages reports prior to August 8, 2006, and in any of its interrogatory responses. Defendants also contend that they identified this device during discovery, even though it was not accused, to be sure that Plaintiff was aware of the device. Defendants also point out that there are no technical reports concerning infringement for this device, and therefore, if Plaintiff is permitted to pursue the device, Defendants contend that discovery will need to be reopened.

Plaintiff contends that Defendants concealed that this device was manufactured in the United States until May 2006. Plaintiff points out that it identified the FSD210 family of products, and the fact that it did not specifically designate the particular sales suffix is a "semantic" difference. According to Plaintiff there is no relevant difference between the FSD210HD and the other members of the FSD210 family, and Defendants' documents demonstrate that the FSD210HD is a version of the FSD210H product identified by Plaintiff. In addition, Plaintiff contends that Defendants, themselves, referred to the FSD210 as an accused device.

The Court concludes that Plaintiff has sufficiently identified the FSD210HD as an accused product in this litigation in light of their identification of the FSD210 family of products. The FSD210 family of products has been the subject of technical expert reports, and therefore, the Court is persuaded that additional discovery related to the FSD210HD product is not required. Further, Defendants have not demonstrated that there is a significant difference between the FSD210HD device and the other devices in that family, including the FSD210H which was identified by Plaintiff. Accordingly, the Court will deny Defendants' Motion.

10. Motion In Limine To Exclude Claims Or Evidence Based On An Alleged "Offer For Sale" Because The Theory Was Not Included In Plaintiff's Damages Report

Defendants contend that Plaintiff's damages expert did not calculate damages based on an offer to sale, and therefore, this evidence is outside the scope of the expert reports. Defendants also contend that offers to sell that culminated in sales outside the United States should be excluded.

Plaintiff contends that lost profit damages are based on lost sales, and therefore, its damages expert was not required to calculate damages separately for offers for sale. However, Plaintiff contends that its damages expert did consider offers for sale in the context of his price erosion calculations. Plaintiff also contends that evidence of offers to sell infringing products in the United States is evidence that actual sales of infringing products occurred in the United States and evidence of Defendants' intent to induce others to imports and use these products in the United States.

*4 The Court has considered the parties' arguments and concludes that the alleged offers to sale were considered by Dr. Troxel in the context of his price erosion analysis and that the alleged offers for sale are relevant to the issues in this case. Accordingly, the Court will deny Defendants' Motion.

11. Motion In Limine To Exclude Doctrine Of Equivalents Arguments With Regard To The '075, '876 And '366 Patent And Limit The Argument With Regard To The '851 Patent

Plaintiff has not asserted the doctrine of equivalents with respect to the '075 patent, and therefore, the Court concludes that the motion is moot to the extent that it pertains to that patent. As for the remaining patents, the Court finds Defendants' motion to be more akin to a motion for summary judgment than a motion in limine, and the question of the sufficiency of the evidence on the doctrine of equivalents can be taken up after the jury's verdict, if necessary. Accordingly, the Court will deny Defendants' Motion to the extent that it has not already been mooted.

12. Motion In Limine To Exclude Evidence Concerning Power Integrations' Earlier Litigation Success Against System General or Motorola

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The parties apparently agree that evidence regarding Plaintiff's successes in the Motorola and System General lawsuits is irrelevant to this action, and therefore, the Court will grant Defendants' Motion. As for Plaintiff's argument that they should be able to raise this issue if Defendants "open the door" to the subject, the Court concludes that such an argument depends entirely on the evidence produced at trial and its context. Accordingly, the Court will address any such issues on a case-by-case basis during the trial.

13. Motion In Limine To Preclude Plaintiff's From Introducing Evidence Of Defendants' Prior Claim Construction Positions, Or Evidence Of Who "Won" Or "Lost"

Defendants contend that any reference to their prior claim construction positions or to who "won" or "lost" the claim construction debate are prejudicial to Defendants and confusing to the jury. In response, Plaintiff contends that this evidence is relevant to willfulness. Specifically, Plaintiff contends that Defendants obtained 13 opinions of counsel and their positions have changed several times, including changes based on incorrect claim construction. Plaintiff contends that they are entitled to question the competence of Defendants' opinions and Defendants' reasonable reliance on those opinions.

While the Court agrees that reference to who "won" or "lost" the claim construction debate may not be appropriate to suggest that the Court favors one parties' position over another, the Court concludes that evidence of Defendants' shifting claim constructions is relevant to the reasonableness and competence of the opinions of counsel relied upon by Defendants as a defense to willful infringement. Accordingly, the Court will permit Plaintiff to explore this issue in that limited context, and therefore, Defendants' Motion will be denied.

14. Motion In Limine To Preclude Any Evidence Or Assertion That Opinion Counsel Must Have Construed All Terms To The Claims As Part Of A Proper Analysis

*5 Plaintiff agrees with Defendants that there is no requirement that opinion counsel construe each and every term of a patent for the opinion of counsel to be valid. However, the Court agrees with Plaintiff that the question of whether counsel should have construed a particular claim term in rendering his

non-infringement opinion is relevant to the jury's assessment of whether Defendants' reasonably relied on that opinion. Accordingly, the Court will deny Defendants' Motion.

15. Motion In Limine To Preclude Irrelevant And Prejudicial Documents Regarding Power Integrations And its Products

Defendants contend that Plaintiff should be precluded from introducing evidence related to awards that Plaintiff has received for its products and evidence from an e-mail sent by one of Defendants employees' which states that Plaintiff's "system ideas" were "epoch making." Defendants contend that this evidence does not have a nexus to the technology or inventions of the asserted claims, and that Plaintiff has not provided any testimony linking these accolades to the patents-in-suit. Defendants further contend that this evidence is more appropriately reserved for the invalidity trial as evidence of secondary indicia of non-obviousness.

Plaintiff contends that the e-mail from Defendants' employee is relevant evidence of Defendants' intent to copy. Plaintiff also contends that the article discussing the awards Plaintiff has received discusses the features of certain of Plaintiff's products which embody the patented technologies in this case.

The Court has reviewed the documents cited by Defendants and concludes that they are relevant to the patented technology and provide useful background information regarding Power Integrations and the marketplace for power supplies. Further, as Plaintiff points out, the Court will instruct the jury as to the appropriate law, so as to prevent the misuse of the documents by the jury, and therefore, the Court is not persuaded that Defendants will suffer undue prejudice if the Court does not exclude the above-referenced documents from evidence. Accordingly, the Court will deny Defendants' Motion.

16. Motion In Limine To Exclude Technical Expert Testimony From Michael Shields On Inherency

Defendants contend that the Court should exclude the testimony of Mr. Shields on the issue of inherency. Specifically, Defendants contend that this testimony exceeds the scope of Mr. Shield's expert report and is beyond his area of expertise. Defendants also contend that Mr. Shields indicated at his deposition that he would not be discussing the subject of inherency.

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In response, Plaintiff contends that Defendants have mischaracterized the testimony of Mr. Shields. According to Plaintiff, Mr. Shields indicated that he did not agree with Defendants' definition of inherency, but did not testify that he would not opine on inherency. Plaintiff also contends that Defendants will have ample opportunity to cross-examine and rebut Mr. Shields' testimony. ^{FN2}

FN2. Plaintiff raises an additional issue which they contend is related to Defendants' Motion. Specifically, Plaintiff contends that Defendants "may" argue that Mr. Shields should not be allowed to provide testimony regarding documents that came to light after Mr. Shields provided his rebuttal report and deposition. Plaintiff requests that the Court clarify that its expert, Mr. Shields, will be permitted to respond to the testimony of Defendants' expert, Mr. Gwozdz, whose testimony the Court declined to preclude in the context of a previous motion in limine raised by Plaintiff. Because this issue was raised in Plaintiff's response to Defendants' Motions In Limine, the Court does not have Defendants' position with respect to this issue. Also, it appears to the Court that Plaintiffs are anticipating this argument to be raised by Defendants, but it is unclear to the Court whether Defendants are, in fact, pressing this argument. Accordingly, the Court will address this issue during the trial, if it becomes necessary.

*6 Plaintiff does not address the content of Mr. Shields report in its response to Defendants' Motion In Limine. The Court has reviewed the report and notes that it does not expressly address the concept of inherency. As the Court stated previously, opinions not disclosed by an expert in his report will not be permitted at trial. Accordingly, the Court will exclude the testimony of Mr. Shields as it relates to the concept of inherency, unless Plaintiff can designate the portion of Mr. Shields' report which it contends addresses this topic, and therefore, Defendants' Motion will be granted at this juncture.

17. Motion In Limine To Exclude E-Mails Between GE And Fairchild

Defendants contend that e-mails between themselves and GE should be excluded from evidence, because

they are irrelevant. Specifically, Defendants contend that the e-mails were not relied upon by Plaintiff's damages expert and were dated prior to October 20, 2004. Defendants also contend that the e-mails have not been authenticated and are inadmissible hearsay.

Plaintiff contends that the e-mails are not relevant to their damages case, but to show Defendants' intent to induce others to import infringing products into the United States. As for authentication, Plaintiff contends that the documents are Defendants' documents, and therefore, Defendants should be required to authenticate them. Plaintiff also contends that these documents are admissible as admissions of a party-opponent and business records.

The Court has reviewed the parties' arguments and the proffered evidence and concludes that the documents referred to by Defendants have only marginal, if any, relevance to the issues in this case. Accordingly, the Court will grant Defendants' Motion and exclude the e-mail evidence referred to by Defendants.

18. Motion In Limine To Exclude Dr. Eklund's Testimony Concerning Conception Or Reduction To Practice Unless Plaintiff Provides And Lays The Foundation Of Independent Evidence Corroborating The Dates

The Court has reviewed the parties' arguments regarding this issue and notes that a related summary judgment motion was denied. The Court further finds that questions concerning conception, reduction to practice and corroboration are factual in nature, and therefore, reserved for the jury. Accordingly, the Court will deny Defendants' Motion.

19. Motion In Limine To Exclude Argument Or Evidence Challenging The Publication Dates Of Prior Art References Listed By Defendants

In an effort to facilitate the resolution of the parties' dispute concerning the publication dates of the prior art references, the Court will limit Defendants to 7 prior art references (a number equaling the number of claims asserted in this litigation). Once the references are selected, the parties shall confer to determine whether they can stipulate to the publication dates. Accordingly, Defendants' Motion will be denied at this juncture.

B. Plaintiff's Motions In Limine (D.I.343-1)

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1. Motion In Limine To Preclude Defendants From Referencing Or Introducing Evidence Related To Plaintiff's Restatement Of Earnings, Including Reference to SEC or DOJ Investigations, Civil Suits Against Plaintiff, and Personnel Changes

*7 The Court has reviewed the parties' positions with respect to this issue and agrees with Plaintiff that the evidence sought to be precluded is irrelevant to this case. As the Court has stated previously, this case is not a securities action. Accordingly, the Court will grant Plaintiff's Motion.

2. Motion In Limine To Preclude Defendants From Arguing That The FSD210HD Devices Were Not Manufactured In The United States

Because the Court will permit Plaintiff to pursue the FSD210HD as an accused device, the Court will also permit Defendants the opportunity to argue that these devices were not manufactured in the United States, if they have evidence to support that argument. Accordingly, the Court will deny Plaintiff's Motion.

3. Motion In Limine To Preclude Testimony From Gu-Yeon Wei, Defendants' expert on copying

Plaintiff contends that Dr. Wei did not speak to those who developed the accused parts and only looked at the circuits and schematics in formulating his opinion on copying. Thus, Plaintiff contends that Dr. Wei's testimony regarding copying is based on speculation. In the Court's view, any deficiencies in the Dr. Wei's opinions, including the measures he took in formulating those opinions, can be addressed by Plaintiff through cross-examination. Accordingly, the Court will deny Plaintiff's Motion.

4. Motion In Limine To Preclude Mr. Conrad, Defendants' "reliance" witness, from testifying regarding communications with Defendants' in-house counsel (Steven Schott) regarding infringement or the validity of the patents-in-suit

Plaintiff contends that during his first deposition, Mr. Conrad indicated that he relied only on certain opinion letters of counsel in connection with Fairchild's defense to the charge of willful infringement; however, Mr. Conrad reversed course during a second deposition and referred to conversations he had with

Mr. Schott. Plaintiff points out that Mr. Schott was initially listed by Defendants as a trial witness, but that when Plaintiff sought to compel his testimony, Defendants took him off the witness list prompting Plaintiff to withdraw its motion to compel. Plaintiff contends that, to the extent Mr. Conrad refers to conversations he had with Mr. Schott, Defendants are trying to introduce Mr. Schott's testimony through the "back-door" while simultaneously having shielded Mr. Schott from discovery.

Defendants contend that Plaintiff had ample opportunity to explore the state of mind of Mr. Conrad during his two day deposition. Defendants contend that Plaintiff's decision not to depose Mr. Schott is not a basis to limit Mr. Conrad's testimony.

The Court agrees with Defendants that Plaintiff made a tactical decision to forgo the deposition of Mr. Schott, and Defendants should not be penalized by that decision. Accordingly, the Court will deny Plaintiff's Motion.

III. Defendants' Motion To Strike Plaintiff's Second Supplemental Report On Damages (D.I.314)

Defendants request the Court to strike the second supplemental expert report of Plaintiff's damages expert, Mr. Troxel, which was served on August 8, 2006. Defendants contend that the report is (1) untimely, (2) accuses a new device, the FSD210HD, that was not previously raised by Plaintiff, (3) contains damages calculations based on conditions occurring before October 20, 2004, (4) adjusts the future lost profits damages sought from 2009 until 2010, (5) improperly contains damages calculations based on worldwide sales, (6) improperly refers to the favorable decision Power Integrations obtained in the ITC investigation of System General, and (7) contains unfair updated references to the testimony and reports of Mr. Slayton and Mr. Lum. In addition, Defendants contend that they have not been able to finish deposing Mr. Troxel and that the damages trial should be continued, because Plaintiff's have not yet produced their restated financial reports.

*8 Plaintiff contends that the FSD210HD is a particular version of a product that has been named as an accused product and within a family of products already identified as accused products. Plaintiff contends that the alternative calculations regarding conditions prior to October 20, 2004, are in Mr. Troxel's report, in case the Court grants reconsideration of its ruling on the markings issue as it

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relates to damages. Plaintiff also contends that Mr. Troxel has always included a future price erosion analysis for a period of four years from the trial date, and therefore, the extension until 2010 reflects the current trial date. Plaintiff further contends that the other changes to the expert report are appropriate and consistent with their duty to provide updated reports in response to newly discovered information.

The Court has reviewed the revisions to Mr. Troxel's report and concludes that the report should be redacted to comport with the Court's rulings in this case regarding the testimony of Mr. Lum and the calculation of damages prior to October 20, 2004. The Court also concludes that the findings of the ITC are irrelevant to this litigation, and thus, those portions of Mr. Troxel's report dealing with the ITC findings should also be redacted. However, the Court will permit damages to be recoverable until 2010, since that is consistent with the period of damages sought by Plaintiff throughout this case and has only changed as a result of the extended trial date. In addition, the Court will allow the report to stand as it pertains to the issue of world-wide sales numbers and the FSD210HD product, which the Court has concluded was properly asserted by Plaintiff as an accused product. Accordingly, Defendants' Motion will be granted-in-part and denied-in-part. Plaintiff's Second Supplemental Expert Report On Damages will be redacted consistently with the Court's rulings in this case.

CONCLUSION

For the reasons discussed, the Court has made the above rulings with respect to the pending Motions.

An appropriate Order reflecting the Court's rulings will be entered.

ORDER

At Wilmington, this 20 day of September 2006, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Defendants' Motion For Protective Order Regarding Deposition Of Michael C. Keeley, Rebuttal Expert Report On Damages And Continuation Of Damages Trial (D.I.309) is *DENIED AS MOOT* to the extent it applies to Mr. Keeley's deposition and *DENIED* in all

other respects.

2. Defendants' Motion In Limine (D.I.356-1) To Exclude Plaintiff's Claim For Damages Based On Defendants' Non-infringing Foreign Sales And Manufacture Of Products That Never Entered the U.S. is *DENIED*.

3. Defendants' Motion In Limine To Exclude Plaintiff's Claim For Evidence And Damages Based On Third Party Alleged U.S. Importation Of Accused Products (D.I.356-2) is *DENIED*.

4. Defendants' Motion In Limine To Preclude Plaintiff From Relying On Decertified Financial Reports (D.I.356-3) is *DENIED*.

*9 5. Defendants' Motion In Limine To Exclude Evidence Of Alleged "Price Erosion" (D.I.356-4) is *DENIED*.

6. Defendants' Motion In Limine To Exclude All Evidence Of Damages Or Notice Prior To October 20, 2004 (D.I.356-5) is *DENIED*.

7. Defendants' Motion In Limine To Exclude Sales Reports And Other Documents As Unreliable (D.I.356-6) is *DENIED*.

8. Defendants' Motion In Limine To Exclude Legal Opinions On Infringement (D.I.356-7) is *DENIED*.

9. Defendants' Motion In Limine To Exclude Evidence That Defendants Copied Plaintiff's Circuits Or Datasheets (D.I.356-8) is *DENIED*.

10. Defendants' Motion In Limine To Exclude Claims And Evidence Regarding Defendants' FSD210HD Product (D.I.356-9) is *DENIED*.

11. Defendants' Motion In Limine To Exclude Claims Or Evidence Based On An Alleged "Offer For Sale" Because The Theory Was Not Included In Plaintiff's Damages Report (D.I.356-10) is *DENIED*.

12. Defendants' Motion In Limine To Exclude Doctrine Of Equivalents' Arguments With Regard To The '075, '876 And '366 Patent And Limit The Argument With Regard To The '851 Patent (D.I.356-11) is *DENIED AS MOOT* as it pertains to the '075 patent, and *DENIED* in all other respects.

13. Defendants' Motion In Limine To Exclude Evidence Concerning Power Integrations' Earlier Litigation Success Against System General or

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Motorola (D.I.356-12) is *GRANTED*.

14. Defendants' Motion In Limine To Preclude Plaintiffs From Introducing Evidence Of Defendants' Prior **Claim Construction** Positions, Or Evidence Of Who "Won" Or "Lost" (D.I.356-13) is *DENIED*.

15. Defendants' Motion In Limine To Preclude Any Evidence Or Assertion That Opinion Counsel Must Have Construed All Terms To The Claims As Part Of A Proper Analysis (D.I.356-14) is *DENIED*.

16. Defendants' Motion In Limine To Preclude Irrelevant And Prejudicial Documents Regarding Power Integrations And its Products (D.I.356-15) is *DENIED*.

17. Defendants' Motion In Limine To Exclude Technical Expert Testimony From Michael Shields On Inherency (D.I.356-16) is *GRANTED*.

18. Defendants' Motion In Limine To Exclude E-Mails Between GE And Fairchild (D.I.356-17) is *GRANTED*.

19. Defendants' Motion In Limine To Exclude Dr. Eklund's Testimony Concerning Conception Or Reduction To Practice Unless Plaintiff Provides And Lays The Foundation Of Independent Evidence Corroborating The Dates (D.I.356-18) is *DENIED*.

20. Defendants' Motion In Limine To Exclude Argument Or Evidence Challenging The Publication Dates Of Prior Art References Listed By Defendants (D.I.356-19) is *DENIED*.

21. Plaintiffs' Motion In Limine To Preclude Defendants From Referencing Or Introducing Evidence Related To Plaintiffs' Restatement Of Earnings, Including Reference to SEC or DOJ Investigations, Civil Suits Against Plaintiff, and Personnel Changes (D.I.343-1) is *GRANTED*.

22. Plaintiffs' Motion In Limine To Preclude Defendants From Arguing That The FSD210HD Devices Were Not Manufactured In The United States (D.I.343-2) is *DENIED*.

*10 23. Plaintiffs' Motion In Limine To Preclude Testimony From Gu-Yeon Wei, Defendants' expert on copying (D.I.343-3) is *DENIED*.

24. Plaintiffs' Motion In Limine To Preclude Mr. Conrad, Defendants' "reliance" witness, from testifying regarding communications with Defendants'

in-house counsel (Steven Schott) regarding infringement or the validity of the patents-in-suit (D.I.343-4) is *DENIED*.

25. Defendants' Motion To Strike Plaintiff's Second Supplemental Report On Damages (D.I.314) is *GRANTED-IN-PART* and *DENIED-IN-PART*. Plaintiff's Second Supplemental Report On Damages will be redacted to comport with the Court's rulings in this case.

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Briefs and Other Related Documents ([Back to top](#))

- [2006 WL 3223651](#) (Verdict, Agreement and Settlement) Special Verdict Form (Oct. 10, 2006) Original Image of this Document (PDF)
- [2006 WL 3227273](#) (Verdict, Agreement and Settlement) Defendants' Special Verdict Form (on Infringement and Damages) (Sep. 1, 2006)
- [2006 WL 3227274](#) (Verdict, Agreement and Settlement) Defendants' Special Verdict Form (on Invalidity) (Sep. 1, 2006)
- [2006 WL 3227272](#) (Trial Motion, Memorandum and Affidavit) Defendants' Motion to Compel Damages Discovery and to Continue Damages Trial Date (Aug. 3, 2006)
- [2006 WL 3227271](#) (Trial Motion, Memorandum and Affidavit) Fairchild's Answering Brief in Opposition to Power Integrations' Motion for Reconsideration of the Court's June 2, 2006 Order (Jul. 6, 2006)
- [2006 WL 1813959](#) (Trial Motion, Memorandum and Affidavit) Intersil Corporation's Opening Brief in Support of its Motion to Quash Subpoena and for Protective Order (May 26, 2006) Original Image of this Document (PDF)
- [2006 WL 3227269](#) (Trial Motion, Memorandum and Affidavit) Consolidated Reply in Support of Defendants' Motions for Summary Judgment (Apr. 19, 2006)
- [2006 WL 3227270](#) (Trial Motion, Memorandum and Affidavit) Reply Brief in Support of Defendants' Motion for Summary Judgment of Limitation on Damages Under 35 U.S.C. 287 (Failure to Mark) (Apr. 19, 2006)
- [2006 WL 1199891](#) (Trial Motion, Memorandum and Affidavit) Opening Brief in Support of Defendants' Motion for Summary Judgment of Unenforceability and Invalidity of U.S. Patent Nos. 6,107,851 and 6,229,366 (Mar. 24, 2006) Original Image of this Document (PDF)

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- 2006 WL 1199892 (Trial Motion, Memorandum and Affidavit) Opening Brief in Support of Defendants' Motion for Partial Summary Judgment of Non-Infringement (Foreign Sales) (Mar. 24, 2006) Original Image of this Document (PDF)
- 2006 WL 1199893 (Trial Motion, Memorandum and Affidavit) Opening Brief Insupport of Defendants' Motion for Summary Judgment of Invalidity of Claim 1 of the '876 Patent (Mar. 24, 2006) Original Image of this Document (PDF)
- 2006 WL 1199894 (Trial Motion, Memorandum and Affidavit) Opening Brief in Support of Defendants' Motion for Partial Summary Judgment of Limitation on Damages under 35 U.S.C. §287 (Failure to Mark) (Mar. 24, 2006) Original Image of this Document (PDF)
- 2006 WL 1199888 (Trial Motion, Memorandum and Affidavit) Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of Claims 1 and 5 of U.S. Patent No. 4,811,075 (Mar. 23, 2006) Original Image of this Document (PDF)
- 2006 WL 1199889 (Trial Motion, Memorandum and Affidavit) Opening Brief in Support of Defendants' Motion for Summary Judgment of Non-Infringement of U.S. Patent No. 4,811,075 (Mar. 23, 2006) Original Image of this Document (PDF)
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- 2006 WL 3226493 () Declaration of Dr. Peter Gwozdz in Support of Defendants' Motion for Summary Judgment Regarding Invalidity of Claims 1 and 5 of U.S. Patent No. 4,811,075 (Mar. 17, 2006) Original Image of this Document (PDF)
- 2006 WL 1199887 (Trial Pleading) Plaintiff Power Integrations, Inc.'s Answer to Defendants' First Amended Counterclaims (Mar. 15, 2006) Original Image of this Document (PDF)
- 2006 WL 3227268 (Trial Pleading) Defendants Fairchild Semiconductor International, Inc. and Fairchild Semiconductor Corporation's First Amended Answer and Counterclaims to Plaintiff's First Amended Complaint for Patent Infringement and Demand for Jury Trial (Feb. 23, 2006)
- 2006 WL 809151 (Trial Pleading) Defendants Fairchild Semiconductor International, Inc. and Fairchild Semiconductor Corporation's First Amended Answer and Counterclaims to Plaintiff's First Amended Complaint for Patent Infringement and Demand for Jury Trial (Feb. 23, 2006) Original Image of this Document (PDF)
- 2006 WL 809150 (Trial Motion, Memorandum and Affidavit) Paul Horowitz's Response and Objections

- to Subpoena (Feb. 3, 2006) Original Image of this Document (PDF)
- 2006 WL 809149 (Trial Pleading) Plaintiff's Answer to Defendants' Motion to Compel the Continued Depositions of Leif Lund and Balu Balakrishnan (Feb. 2, 2006) Original Image of this Document (PDF)
- 2005 WL 4883954 (Trial Pleading) Power Integrations' Opening Claim Construction Brief (Dec. 28, 2005)
- 2005 WL 3666891 (Trial Motion, Memorandum and Affidavit) Plaintiff's Consolidated Opposition to Defendants' Expedited Motion to Amend the Schedule and Motion to Shorten Time (Oct. 28, 2005) Original Image of this Document (PDF)
- 2005 WL 4883959 (Trial Motion, Memorandum and Affidavit) Defendants'd Answering Brief in Opposition to Plaintiff's Motion for Clarification or Reconsideration (Sep. 7, 2005)
- 2005 WL 4883958 (Trial Motion, Memorandum and Affidavit) Plaintiff's Opening Brief in Support of Its Motion for Clarification or, in the Alternative, Reconsideration of the Court's August 9, 2005 Order (Aug. 23, 2005)
- 2005 WL 4883957 (Trial Motion, Memorandum and Affidavit) Plaintiff's Opposition to Defendants' First Motion to Compel (Aug. 12, 2005)
- 2005 WL 4883956 (Trial Pleading) Answer (Aug. 1, 2005)
- 2005 WL 4883955 (Trial Pleading) Defendants Fairchild Semiconductor International, Inc.'s and Fairchild Semiconductor Corporation's Answer and Counterclaims to Plaintiff's First Amended Complaint for Patent Infringement and Demand for Jury Trial (Jul. 11, 2005)
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- 2004 WL 5027306 (Verdict, Agreement and Settlement) Power Integrations' "Proposed" Special Verdict and Interrogatories to the Jury (2004)

END OF DOCUMENT

EXHIBIT 13



US006686191B1

(12) **United States Patent**
Alonso

(10) Patent No.: **US 6,686,191 B1**
(45) Date of Patent: **Feb. 3, 2004**

(54) **PREPARATION OF VIRALLY INACTIVATED
INTRAVENOUSLY INJECTABLE IMMUNE
SERUM GLOBULIN**

(75) Inventor: William R. Alonso, Cary, NC (US)

(73) Assignee: Bayer HealthCare LLC, Tarrytown,
NY (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 1772 days.

(21) Appl. No.: 08/532,211

(22) Filed: Sep. 22, 1995

(51) Int. CL⁷ C12N 7/04; A61K 39/395;
A61K 39/40; A61K 39/42

(52) U.S. CL 435/236; 424/176.1; 424/177.1;
424/130.1

(58) Field of Search 530/390.1, 390.5,
530/386, 387.1; 424/176.1, 177.1, 130.1;
435/236

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,396,608 A * 8/1983 Tenold
4,540,573 A * 9/1985 Neurath et al.
4,762,714 A * 8/1988 Mitra et al.

OTHER PUBLICATIONS

Joy Yang, Y.H. et al. "Antibody Fc functional activity of
intravenous immunoglobulin preparations treated with sol-
vent-detergent for virus inactivation" Vox Sang, vol. 67, pp.
337-344, May 17, 1994.*

* cited by examiner

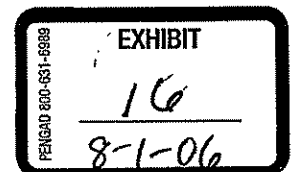
Primary Examiner—Yvonne Eyley

(74) Attorney, Agent, or Firm—Connolly Bove Lodge &
Hutz LLP

(57) **ABSTRACT**

Method of reducing the anticomplement activity (ACA)
resulting from viral inactivation treatment of a solution of
antibodies, the method comprising contacting the solution
with a trialkylphosphate, such as tri-n-butyl phosphate, and
a detergent, such as sodium cholate, under conditions suf-
ficient to reduce substantially the virus activity, and then
incubating the solution under controlled conditions of time,
pH, temperature, and ionic strength such that the anti-
complement activity is reduced to an acceptable level. In a
preferred embodiment, the ACA is reduced to less than 60
CH₅₀ units/mL, the incubation is for at least about ten days
at a pH from 3.5 to 5.0, the temperature is maintained within
a range of 2 to 50° C., and the ionic strength of the solution
is less than about 0.001 M.

24 Claims, 1 Drawing Sheet

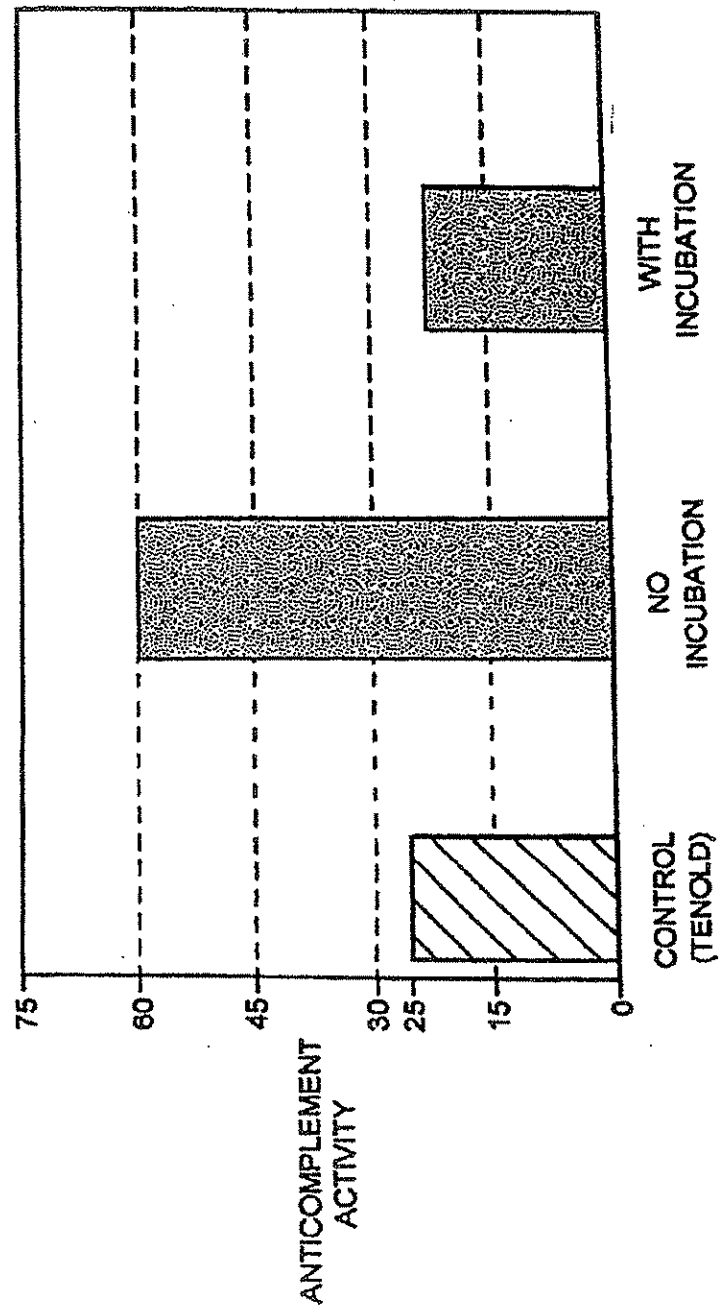


DS Pro

U.S. Patent

Feb. 3, 2004

US 6,686,191 B1



US 6,686,191 B1

PREPARATION OF VIRALLY INACTIVATED INTRAVENOUSLY INJECTABLE IMMUNE SERUM GLOBULIN

BACKGROUND OF THE INVENTION

1. Field

This invention generally deals with an intravenously injectable immunoglobulin product, and more specifically deals with an intravenously injectable immune serum globulin (IGIV) which has been subjected to a virus inactivation step and which has a low level of anticomplement activity.

2. Background

Early pharmaceutical preparations of immune serum globulins could not be administered intravenously due to an unacceptably high incidence of adverse reactions. These adverse reactions were associated with a decrease in serum complement levels, apparently caused by complement binding to the administered gamma globulin. (1) The ability of gamma globulin to bind complement, or its anticomplement activity (ACA), is greatly increased as a result of denaturation brought about during the fractionation procedure. Several approaches have been taken to address the problem of rendering ISG safe for intravenous administration. (See (2) and references therein). Tenold reported a method of preparing an immune serum globulin (ISG) with low ACA which could be administered by intravenous injection. (2, incorporated herein by reference). The Tenold '608 process requires formulating the ISG at low ionic strength (preferably less than about 0.001) and at low pH (3.5-5.0).

Other methods of preparing intravenously injectable immune serum globulin (IGIV) have been reported, including stabilizing with carbohydrates such as maltose (3). A process including incubation of ISG at pH 4.0 at 37° C. (4) results in a product with low ACA which may be administered by intravenous injection; however, upon storage the product regains its high ACA. IGIV has also been prepared by covalent modification of the ISG, for example by proteolysis (5) or by reduction of disulfide linkages followed by reaction with a blocking agent (1,6).

Antibody preparations, since they are isolated blood products, have an inherent hazard of transmitting virally-mediated diseases. Inactivation of viruses is an important step in producing safe and effective blood products. U.S. Pat. No. 4,540,573 to Neurath et al., which is incorporated herein by reference, describes a viral inactivation process using a trialkyl phosphate and detergent process (hereinafter, the solvent/detergent process, or SD process). (7) That solvent/detergent method has gained acceptance as being efficacious in the inactivation of lipid-enveloped viruses with limited adverse effects on biological activity or blood product profile. (8, 15; See also 12 for a discussion of various viral inactivation processes).

Current antibody preparations on the market generally have been regarded as safe with respect to viral contamination. (9) This is thought to be due to features of the fractionation processes used to isolate these blood products. However, it would be desirable to further ensure the safety of the antibody preparations by including a distinct viral inactivation step in the production process. Successful reduction of viral activity in an IGIV solution was reported using several different methods of viral inactivation for a variety of viruses. (16, 17) A process for preparation of immunoglobulins substantially free of retrovirus has been reported involving incubation of ISG under controlled conditions of time, temperature, and pH. The process entails

isolating ISG via a cold ethanol plasma fractionation process and then storage of the ISG at one of two storage conditions: (a) at pH ≤ 4.25 at a temperature of 27° C. for at least three days, or (b) at pH ≤ 6.8 at a temperature of 45° C. for at least six hours. (10).

We have found that using the SD process to treat ISG preparations, especially those subsequently formulated according to the Tenold '608 patent, results in a product with an acceptable viral inactivation but with unacceptably high levels of ACA. Elevated ACA levels were always detected at the sterile bulk stage (i.e., after compounding as 5% or 10% IGIV and filtration with 0.2 μ m sterile filters) of all tri-n-butyl phosphate (TNBP)/detergent treated IGIV preparations regardless of process scale. Preparations of ISG with high ACA levels are not suitable for intravenous injection and instead must be administered via other routes, e.g. intramuscular (IM) injection. However, IGIV preparations are more desirable since they are immediately available in the bloodstream and are not subject to loss associated with IM injection. It is thus desirable to have an IGIV product which is both low in ACA and has been subjected to a viral inactivation step.

SUMMARY OF THE INVENTION

The invention is a method for producing an intravenously injectable immune serum globulin (IGIV) preparation with low anticomplement activity which has been chemically treated to render it substantially free of lipid-enveloped viruses. The method comprises a solvent/detergent viral inactivation step followed by an incubation step. We have discovered that the incubation step is necessary to achieve an acceptable level of ACA low enough to allow the ISG to be administered by intravenous injection. The incubation step should be conducted under controlled time, pH, temperature, and ionic strength. Preferably, the pH should be maintained between about 3.5 and about 5.0, the temperature should be within a range of about 2 to about 50° C., and the ionic strength should be less than about 0.001M. In a preferred embodiment the ACA of the ISG preparation decreases gradually over a period of at least about ten days when the ISG is maintained at a pH of about 4.25 at low ionic strength (less than about 0.001M) and the viral inactivation step (in a model system) results in a substantial reduction (i.e. at least 4 logs) in the titer of lipid enveloped viruses.

BRIEF DESCRIPTION OF THE FIGURE

FIG. 1 shows a comparison of the typical average observed ACA levels of 5% IGIV solutions treated according to the SD process and with or without the follow-up incubation of the present invention.

SPECIFIC EMBODIMENTS

Materials and Methods

The starting material for the process of this invention is unmodified human immune serum globulin. In the specification and claims the term "immune serum globulin" is used to define the substance also referred to in the literature variously as gamma globulin, IgG and immunoglobulin G. It consists predominantly and preferably of at least about 85 percent of the 7S species of gamma globulin, which has a molecular weight of about 160,000. Any remainder is preferably 9S species, with a molecular weight of about 300,000. Both standard immune and hyperimmune serum globulins, e.g., tetanus, rabies and hepatitis immune serum globulins,

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can be employed, the solvent/detergent treated product being immune and hyperimmune ISG, respectively. Thus, a suitable starting material for the process of this invention is Cohn's Fraction II or Fraction III filtrate. (See Refs. 13, 14.)

Fraction II, by ultracentrifugation studies, is predominantly (about 85 percent) the 7S (sedimentation constant of 7) species of gamma globulin with an average molecular weight of 160,000. The remaining protein is essentially 9S material with a M.W. of about 300,000. Wet Fraction II paste (approximately 30 percent solids) is commonly lyophilized to obtain dry ISG powder which is then dissolved and prepared for intramuscular injection as a 16.5 percent sterile solution. Either the wet Fraction II paste or the dry ISG powder is a suitable starting material for the process of this invention.

Gamma globulin obtained by any process which has essentially the same composition of protein components as found in the Cohn Fraction II or Fraction III filtrate can be used as starting material in the present process. Both standard immune serum globulin and hyperimmune serum globulin can be employed as starting materials. As is well known, the latter is produced from plasma or serum obtained from selected donors who have much higher titers for a specific antibody than is normally found in the average population. These donors have either been recently immunized with a particular vaccine or else they have recently recovered from an infection or disease. These high titer sera or plasmas are pooled and subjected to the usual Cohn fractionation procedures up to the point of isolating Fraction II.

Furthermore, because the amount of antibody required to achieve a desired immunological response is substantially less when administered intravenously, it will be apparent the intravenous dose will be substantially less than the intramuscular dose which will produce the same serum antibody titer. Thus, the dose of intramuscular ISG and hyperimmune serum globulin must be higher than that required to achieve the same serum antibody titer when globulin of the same antibody activity is administered intravenously.

The starting wet paste or lyophilized powder is dissolved in a volume of water or other physiologically-acceptable carrier to provide a protein solution of a concentration of about 0.5-20% preferably about 5 to 10 percent. If Fraction III filtrate is employed, the aqueous solution must be concentrated by conventional techniques to the desired protein concentration. Any protein concentration may be used in this method; however, the above range is preferred from a practical standpoint.

After the protein has been dissolved or concentrated, the solution is adjusted to a pH of about 3.5 to 5.0 preferably about 3.8 to 4.2, by addition of a physiologically-acceptable acid such as hydrochloric acid. In general, the pH is adjusted to a point whereat the monomeric material in the protein solution is maintained at a maximum. However, the pH must not be so low as to result in gelation. The temperature should not be harmful to the ISG material. Good results are obtained within the temperature range of about 0-20° C. It is not necessary to hold the so-adjusted material for any period of time prior to the next step; however, the material may be held, if desired, without detrimental effects.

The protein solution at the appropriate pH (preferably 3.8-4.2) may be diafiltered with at least 4 volume exchanges of water to reduce the alcohol concentration from approximately 17% (Filtrate III) to about 2% alcohol. The efficacy of solvent/detergent as a viral inactivation method is much better at or above ambient temperatures; however, high

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concentrations of alcohol at these temperatures will denature the IgG molecules. Thus, this inactivation must be performed in low alcohol concentration.

Next, the protein concentration of the so-treated material is adjusted to the level desired for incubation with TNBP/detergent, generally less than 10% protein for maximum viral inactivation. This adjustment is accomplished by conventional techniques not detrimental to ISG, e.g., ultrafiltration, reverse osmosis, sublimation, evaporation, etc. Prior to addition of TNBP/detergent, the pH may be adjusted within a wide range, depending on the detergent to be used. With Tween 80, the pH may be as low as 3.5, where the IgG starts becoming unstable. With cholate, the pH is adjusted to within the range of 5.0-6.4, preferably about 5.6, prior to addition of TNBP/detergent. Satisfactory cholate solubility during incubation was achieved by adjusting the immunoglobulin solutions to a pH of 5.5 or higher prior to addition of TNBP and sodium cholate. Adjusting the IgG solution to pH values lower than 5.5 is not suitable because the solubility of sodium cholate is highly dependent on pH (cholic acid $pK=6.4$), with poor solubility at pH 5.5 or lower. Furthermore, maximum viral inactivation during incubation with TNBP/cholate was observed at pH values less than 6.0 in experiments which employed model viruses spiked into IgG solutions. The inactivation of HIV-1 and BVDV (bovine viral diarrhea virus, which is employed as a model for hepatitis C) was accelerated at pH 5.8, with inactivation to the detection limit occurring in 1-2 hours, whereas inactivation to the detection limit required a minimum of 6 hours when pH 7 conditions were used.

Next, the TNBP/detergent is added to the protein solution (preferably less than 8% [w/w], pH 5.8) mixed thoroughly, and then incubated above ambient temperatures, for example 30° C., with continuous agitation or mixing. Target TNBP/cholate levels for optimal viral inactivation during the incubation step should be >3 mg/mL TNBP and >2 mg/mL cholate as defined by Edwards et al. (8). Moreover, for effective viral inactivation, it is important that the solution is essentially free of particulates in order to facilitate thorough mixing of solvent/detergent and IgG solution. After incubation with TNBP/cholate under these conditions, greater than 5.2 \log_{10} reduction of HIV-1 and greater than 4.0 \log_{10} reduction of BVDV were detected.

After completing the incubation which provides the viral inactivation, the solvent and detergent molecules must be removed in order to achieve a final product with low levels of residual TNBP and cholate which would be suitable for intravenous administration. Generally, procedures to remove detergent are also effective in removing TNBP, and vice versa. Very low levels of TNBP and cholate in the final container can be achieved by a combination of filtration, diafiltration and hydrophobic chromatography. After completing the incubation, the majority of cholate (and TNBP) can be removed from the protein solution by filtration, providing the solution had been previously adjusted to a lower pH value such as 4.0, because sodium cholate is sparingly soluble in aqueous solutions at such pH values. Moreover, all processing steps which follow the solvent/detergent incubation are performed at lower pH values (i.e., 4.0) because IgG molecules are more stable at pH values between 3.5-5.0, in low ionic strength solutions. (2) Thus, after incubation with TNBP/cholate, the protein solution is adjusted to approximately pH 4.0 and incubated at 0-8° C. in order to promote cholate precipitation. Next, filtration is employed to remove the precipitated cholate from the IgG solution.

The so-treated solution is diafiltered with at least four volume exchanges of water to reduce the ionic strength and

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to remove additional TNBP and cholate. After or during the above treatment, the pH is measured and maintained within the range of about 3.5-5.0. The protein concentration of the so-treated material is adjusted to 10-30%, usually 13% (w/v) by employing conventional techniques not detrimental to ISG, e.g., ultrafiltration, reverse osmosis, sublimation, evaporation, etc. Again the pH of the preparation is maintained within the range of about 3.5-5.0, preferably about 3.8-4.2.

In the present invention, hydrophobic chromatography is employed to remove the TNBP and cholate not eliminated by the filtration and diafiltration steps, and thus provide a final product with low levels of residual TNBP and cholate which is suitable for intravenous administration. Hydrophobic chromatography is a method for TNBP removal from protein solutions that has fewer drawbacks and limitations than other available methods such as oil extraction, ion exchange or affinity chromatography. In part, this is because the protein of interest (IgG) remains in solution throughout the TNBP removal process. Polystyrene-based resins (typically PLRP-S from Polymer Laboratories, Amherst, Mass.) were used to remove the solvent/detergent from solution, as we have found the polystyrene-based resins to be superior to other resins, such as silica-based C-18 resins.

Next, the ISG preparation is adjusted to 5% or 10% protein, and treated to render it tonic, i.e., to render it compatible with physiological conditions, or render it physiologically acceptable upon injection. In a preferred embodiment, the tonicity is adjusted to about 230 to about 490 mosmol/kg solvent. More preferably, the tonicity range is from about 250 to about 350 mosmol/kg solvent, and most preferably the tonicity range is from about 260 to about 325 mosmol/kg solvent. The 5% formulation (5% IGIV) is made tonic by the addition of 10% maltose. The 10% formulation contains 0.2 M glycine in order to achieve an isotonic preparation without large quantities of sugar. The product with either formulation (Gamimune®N 5% or Gamimune®N 10%) experiences shifts in molecular distribution (antibody aggregation) when the ionic strength of the low pH solution is increased. Therefore, sodium chloride, which is often used to achieve tonicity, should not be used.

The so-treated solution is incubated at pH 4.25 under low ionic strength conditions (NLT 21 days at 20-27° C. preferred) in order to provide a lowering of ACA levels. The ionic strength is determined according to Perrin (18), and in a preferred embodiment the ionic strength should be less than about 0.001M. Elevated ACA levels were always detected at this stage of all TNBP/cholate treated IGIV preparations (regardless of process scale); however, ACA levels are gradually lowered by incubation at pH 4.25 under low ionic strength conditions (Tables 3, 5-7). While there is no strict rule for determining when the ACA level is low enough to be an acceptable level suitable for intravenous administration, IGIV preparations should have ACA levels as low as possible.

The Figure depicts the typical average reduction of ACA observed in 5% IGIV solutions following SD treatment. For a 5% ISG formulation the acceptable level suitable for intravenous administration preferably would be less than about 45 CH₅₀ units/mL, and more preferably less than about 30 CH₅₀ units/mL. For a 10% ISG formulation, the acceptable level suitable for intravenous administration preferably would be less than about 60 CH₅₀ units/mL, and more preferably less than about 45 CH₅₀ units/mL. As used herein, one unit of ACA activity (one CH₅₀ unit) is defined as the amount of protein capable of activating 50% of the complement in an optimally titrated complement and red

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blood cell/hemolysis system. The assay measures the amount of complement that is bound by the mixture of standardized amounts of complement and protein. See refs. 19-20 for a discussion of the assay. Briefly, red blood cells that have been sensitized by preincubation with red blood cell antibodies are added to the complement/protein mixture. In the presence of free complement (not already bound by the protein) these sensitized cells will lyse, releasing hemoglobin which can be quantitated as a measure of the degree of lysis. In parallel, sensitized red blood cells are also added to a buffer control-complement mixture, whose degree of lysis is defined as 100%. The difference between the actual amount of complement needed to give 100% lysis and the amount of complement remaining unbound in the presence of protein equals the amount of complement actually bound by the protein, or anticomplement activity.

Results

Anticomplement Activity of ISG Resulting From Viral Inactivation Process

To establish the effect of the SD viral inactivation process on solutions containing ISG which are formulated according to the Tenold '608 patent, the experiments depicted in Table 1 were performed. The starting material (SM) was Cohn process filtrate III which had been ultrafiltered to about 5% protein and then diafiltered with four volumes of water.

In the control experiment, incubation (-)/SD (-), the SM was not subjected to any incubation or solvent/detergent treatment. In the incubation (+)/SD (-) experiment, the pH of the SM was adjusted to 7.0, the solution was incubated at 30° C. for ten hours, and then the pH was reduced to 4.0. In the incubation (+)/SD, TNBP & Tween 80 (+) experiment, the pH of the SM was adjusted to 7.0, 3 mg/mL TNBP and 2 mg/mL Tween 80 were added to the solution, the solution was incubated at 30° C. for ten hours, and then the pH was reduced to 4.0. In the incubation (+)/SD, TNBP & cholate (+) experiment, the pH of the SM was adjusted to 7.0, 3 mg/mL TNBP and 2 mg/mL cholate were added to the solution, the solution was incubated at 30° C. for ten hours, and then the pH was reduced to 4.0. The solutions in each experiment were then diafiltered with four volumes CWFI (cold water for injection) and concentrated by ultrafiltration. After addition of dry maltose to 10% w/v, the 5% IGIV solution (pH 4.25) was filtered through a 0.2 µm filter.

TABLE 1

Anticomplement activity in 5% IGIV produced by variations of the Solvent/Detergent IGIV Process

	ACA (CH ₅₀ /mL)
Control (no solvent/detergent treatment, no 30° C. incubation)	25
Incubate at 30° C. for 10 hr (no solvent/detergent)	22
Incubate at 30° C. for 10 hr NLT 3 mg/mL TNBP	68
NLT 2 mg/mL Tween 80 Incubate at 30° C. for 10 hr	>100
NLT 3 mg/mL TNBP NLT 2 mg/mL cholate	

*These samples were assayed for ACA after final compounding according to the Tenold '608 patent, but they were not incubated at pH 4.25 and 22° C. prior to analysis.

The results listed in Table 1 show that levels of ACA increased in IgG samples after incubation with TNBP/cholate or TNBP/Tween 80. ACA levels were not elevated in IgG samples that were incubated for 10 hr at 30° C. in the

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absence of solvent/detergent. These results suggest that ACA levels of IGIV samples were not elevated by either processing manipulations or incubation for 10 hr at 30° C. in the absence of solvent/detergent.

TABLE 2

Anticomplement activity in 5% IGIV spiked with TNBP/Na cholate	
	ACA (CH ₅₀ /mL)
5% IGIV, no TNBP/cholate	12
5% IGIV with 100 µg/mL TNBP, 100 µg/mL Na cholate	13

Furthermore, spiking experiments (with TNBP and Na cholate, Table 2) have demonstrated that the elevated anticomplement activity levels were not artifacts caused by carrying out the anticomplement assay in the presence of trace levels of TNBP/Na cholate. Thus, using the prior art SD process for viral inactivation of a solution containing ISG, subsequently formulated according to the Tenold '608 patent, yields a product which has high ACA and is unsuitable for intravenous administration. In a similar experiment, SD treated samples which were not incubated (Table 3, Initial Testing) had ACA levels greater than 100 units.

TABLE 3

Reduction in Anticomplement activity of samples previously treated with TNBP/cholate		
ACA (CH ₅₀ /mL)		
Sample	Initial Testing (no incubation)	After incubation 6 wk. @ 5° C. 3 wk. @ 22° C.
RB21872-16	>100	33
RB21872-17	>100	34
RB21872-18	>100	36
RB21872-20	>100	27

However, when duplicate SD treated samples were incubated for extended periods of time (6 weeks at 5° C. and 3 weeks at 22° C.), the level of ACA was markedly reduced (Table 3, after incubation). This led to further investigation of this surprising observation.

Aggregate Content of ISG Exposed to TNBP/cholate

The samples of the previous experiment (Table 3, Initial Testing) were analyzed by size exclusion (gel permeation) HPLC immediately after compounding to determine the extent of aggregation of the IGIV at the initial time point. HPLC analysis shows nearly complete monomer content in the samples. (Table 4).

TABLE 4

HPLC analysis of non-incubated 5% IGIV samples (Table 3 Initial)				
Sample	Aggregate (%)	Dimer (%)	Monomer (%)	Fragment (%)
RB21872-16, initial	0.140	0.00	99.86	0.00
RB21872-17, initial	0.146	0.00	99.85	0.00
RB21872-18, initial	0.124	0.00	99.88	0.00
RB21872-20, initial	0.172	0.00	99.83	0.00

Previously, high IgG aggregate levels were shown to correlate with high anticomplement activity. However, results from analysis of the samples show the level of ACA

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in the samples to be greater than 100 units. (Table 3, 'Initial Testing') The HPLC analysis shows that the high ACA following the TNBP/cholate treatment was not due to the presence of aggregated IgG molecules.

5 Varied Conditions of Time and Temperature

The SM was the same as in the previous experiment, and experimental conditions were similar with the following changes. The solutions were treated with TNBP/cholate at pH 7.0 and then were compounded to 5% IGIV, 10% maltose, pH 4.25, as above. The ACA was assayed immediately after final compounding, after a first incubation for nine days at 5° C., and after a second incubation for 21 days at either 22° C. or 5° C. The results are presented in Table 5.

TABLE 5

ACA of TNBP/cholate treated IGIV samples	
Sample Point	ACA (CH ₅₀ /mL)
<u>Intermediate Samples</u>	
Initial sterile bulk	>100
Incubated 9 d. @ 5° C.	>100
<u>Final Incubation</u>	
21 d. @ 22° C.	49
21 d. @ 5° C.	71

In the initial sterile bulk sample, which was treated with TNBP/cholate at pH 7.0, the level of ACA was again greater than 100 units for the initial time point, confirming the observations noted in Table 3. Upon incubation at 5° C. for nine days, the ACA remained greater than 100 units. The final incubation step at either 5° C. or 22° C. shows that the reduction in ACA is dependent on temperature, with faster reduction in ACA observed at higher temperatures.

Effect of pH During Solvent/detergent Treatment on ACA

ACA levels were evaluated after incubation with TNBP/cholate at pH 5.8 because better viricidal activity was observed at pH values less than 6.0. Generally, the non-incubated sterile bulk samples of material incubated at pH 5.8 had lower ACA levels than the pH 7.0 samples, but the trend of lowering ACA upon incubation was repeated in the pH 5.8 samples. In fact, the ACA levels continue to decrease beyond the 21 day incubation in samples that initially had elevated ACA levels after incubation with TNBP/cholate at pH 5.8 (Table 6). As was previously noted for the samples incubated at pH 7.0, the lowering of ACA was not due to decreasing levels of aggregated IgG molecules because the material treated at pH 5.8 was essentially monomeric IgG prior to 22° C. incubation (HPLC analysis, sample A4, Table 8).

TABLE 6

Sample A4 - ACA upon extended incubation		
Incubation at 22° C. (days)	CH ₅₀ /mL	
0	122	
10	73	
19	55	
25	56	
28	45	
30	40	
34	39	
41	33	

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TABLE 6-continued

Sample A4 - ACA upon extended incubation	
Incubation at 22° C. (days)	CH ₂ O/mL
48	30
55	29

Similar results were achieved with samples formulated to 10% IGIV, 0.2 M glycine in the sterile bulk stage. Upon incubation at low ionic strength at pH 4.25 for 10 and 21 days, the levels of ACA were seen to decline in both 5% IGIV samples and 10% IGIV samples. (Table 7) The decrease in ACA can thus be observed over a range of ISG concentrations and over a range of pH values for the solvent/detergent treatment. (Tables 3, 5, 7) HPLC analysis (Table 8) of the sterile bulk samples presented in Table 7 confirmed that the elevated ACA levels were not due to aggregation of ISG molecules.

TABLE 7

ACA of samples treated with TNBP/cholesterol at pH 5.8			
Sample	Sterile bulk (day zero) (CH ₂ O/mL)	10 days incubation at 20-27° C. (CH ₂ O/mL)	21 days incubation at 20-27° C. (CH ₂ O/mL)
A1 (5% IGIV)	43	ND	10
A2 (5% IGIV)	31	14	15
A3 (5% IGIV)	44	15	12
A4 (5% IGIV)	122	73	55
B1 (10% IGIV)	>100	48	46
B2 (10% IGIV)	49	36	30
B3 (10% IGIV)	53	ND	37

Taken together, the above results suggest that ISG products which have been subjected to a solvent/detergent viral inactivation process resulting in an undesirable ACA increase can be made suitable for IV administration by incorporating an additional incubation step under the conditions described here to reduce the ACA to an acceptable level.

TABLE 8

HPLC Analysis of sterile bulk samples treated with TNBP/cholesterol at pH 5.8				
Sample	Aggregate (%)	Dimer (%)	Monomer (%)	Fragment (%)
A2	0.140	0.00	99.86	0.00
A3	0.146	0.00	99.85	0.00
A4	0.124	0.00	99.88	0.00

CONCLUSION

The ACA increase resulting from the solvent/detergent treatment of the IGIV (antibody) solution appears to be an unavoidable secondary effect of TNBP/detergent treatment to inactivate viruses in the solution. I have discovered that by incubating the solution of IGIV at low pH (4.25) and low ionic strength (0.001M) for a relatively long period of time (at least about 10 days), the ACA gradually decreases over the period of incubation.

The prior art discloses a method of producing IGIV (the Tenold '608 patent) using low pH and low ionic strength.

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The Tenold '608 method omits the viral inactivation step, and thus avoids the problem of increased ACA, but the possibility of viral activity remains. Unlike Tenold, incubation is an essential aspect of the present invention for reducing the ACA.

The Neurath et al. '573 patent teaches the solvent/detergent viral inactivation step. However, Neurath '573 does not mention controlling the pH and also does not mention any consequences of the process relating to ACA. Elevated ACA levels were detected at the sterile bulk stage of TNBP/cholesterol treated IGIV preparations. However, ACA levels decreased upon incubation for at least about 10 days at pH 4.25, low ionic strength, and not less than about 20° C. (See Tables 5-7) The prior art describes several approaches to lowering ACA levels of purified IgG preparations, including removal of IgG aggregates. (1) IgG aggregates have been shown to activate the complement system in vivo. (1) In the present invention, however, lowering of IgG ACA was not due to decreasing levels of IgG aggregates because these TNBP/cholesterol treated IGIV preparations contained low levels of aggregated IgG (as measured by HPLC, Tables 4, 8) prior to incubation under such conditions.

It would be desirable to produce substantially virus-free IGIV, but following the prior art results in a product with an unacceptable level of ACA. Note that Tenold '608 states that the product is substantially free of ACA, but use of the SD process in conjunction with Tenold '608 does result in high levels of ACA: experimental results reported here show that treating ISG solutions with the SD process and then formulation according to the Tenold '608 patent leads to a product with high ACA. (See Tables 1, 3, 5-7) The surprising finding reported here is that a follow-up (terminal) incubation step lowers the ACA of the solvent/detergent treated solution. The typical average observed ACA levels of 5% IGIV solutions treated according to the SD process and with or without the follow-up incubation are compared in the Figure. The present invention thus includes a previously unobserved method of reducing the ACA by incubating under controlled conditions of pH, temperature, and ionic strength for a period of time, thus allowing the product to be administered by intravenous injection.

Mitra '714 does not suggest the use of a S/D process but, instead, reports that a relatively brief incubation of an ISG product under similar conditions results in a substantially virus free preparation. (10) However, employing incubation under such conditions to provide a lowering of anticomplement activity is a novel application of these incubation conditions which were previously employed in the IGIV process for inactivation of enveloped viruses.

The newly developed IGIV process reported here, which includes an additional internationally accepted viral inactivation procedure (treatment with TNBP/cholesterol), generates IgG preparations which have low ACA levels and are suitable for IV administration. The major advantage is that an IGIV product with improved safety can be obtained by a two-step process that includes a TNBP/cholesterol treatment for viral inactivation and incubation under conditions that afford low ACA levels that are suitable for IV administration.

The above disclosure is intended to illustrate the invention, and it is thought variations will occur to those skilled in the art. Accordingly, it is intended that the scope of the invention should be limited only by the claims below.

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 1. A method of treating a solution of antibodies which may have virus activity, the method comprising
 - a) contacting the solution with a trialkylphosphate and a detergent under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity; and
 - b) then incubating the solution of step a) under conditions of controlled time, pH, temperature, and ionic strength, such that the increased anticomplement activity of the solution is reduced to an acceptable level suitable for intravenous administration.
 2. The method of claim 1, wherein the anticomplement activity is reduced to less than about 60 CH₅₀ units/mL.
 3. The method of claim 1, wherein the solution comprises about 5% wt./wt. antibody and the anticomplement activity is less than about 45 CH₅₀ units/mL.
 4. The method of claim 3, wherein the solution comprises about 5% wt./wt. antibody and the anticomplement activity is less than about 30 CH₅₀ units/mL.
 5. The method of claim 1, wherein the solution comprises about 10% wt./wt. antibody and the anticomplement activity is less than about 60 CH₅₀ units/mL.

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6. The method of claim 5, wherein the solution comprises about 10% wt./wt. antibody and the anticomplement activity is less than about 45 CH₅₀ units/mL.
7. The method of claim 1, wherein the incubation is for at least about ten days.
8. The method of claim 1, wherein the pH is maintained within a range of about 3.5 to about 5.0.
9. The method of claim 1, wherein the temperature is maintained within a range of 2° C. to 50° C.
10. The method of claim 1, wherein the ionic strength is less than about 0.001 M.
11. The method of claim 1, wherein at least about 99% of the antibodies are monomeric.
12. The method of claim 1, comprising the further step of adjusting the tonicity of the solution to a physiologic value under such conditions that the ionic strength is not appreciably altered.
13. The method of claim 12, wherein the tonicity of the solution is adjusted by adding a carbohydrate to the solution.
14. The method of claim 13, wherein the carbohydrate used is maltose.
15. The method of claim 12, wherein the tonicity of the solution is adjusted to a range of about 230 to about 490 mosmol/kg solvent.
16. The method of claim 15, wherein the tonicity of the solution is adjusted to a range of about 274 to about 309 mosmol/kg solvent.
17. The method of claim 12, wherein the tonicity of the solution is adjusted by adding an amino acid to the solution.
18. The method of claim 17, wherein the amino acid used is glycine.
19. The method of claim 1, wherein the trialkylphosphate is tri-n-butyl phosphate and the detergent is selected from polysorbate 80 and sodium cholate.
20. The method of claim 1, wherein the solution has a pH between about 3.5 and about 6.0 during step a).
21. An intravenously injectable immune serum globulin preparation produced by the method of claim 1 and substantially free of lipid enveloped viruses, wherein the preparation has an ionic strength less than about 0.001 M, a pH between about 3.5 and about 5.0, an antibody concentration of about 5% wt./wt., and a maltose concentration of about 10% wt./wt.
22. The preparation of claim 21, wherein the pH is about 4.25.
23. An intravenously injectable immune serum globulin preparation produced by the method of claim 1 and substantially free of lipid enveloped viruses, wherein the preparation has an ionic strength less than about 0.001, a pH between about 3.5 and about 5.0, an antibody concentration of about 10% wt./wt., and a glycine concentration of about 0.2 M.
24. The preparation of claim 23, wherein the pH is about 4.25.

* * * * *

EXHIBIT 14

LEXSEE



Analysis
As of: May 05, 2007

KSR INTERNATIONAL CO., PETITIONER v. TELEFLEX INC. ET AL.

No. 04-1350

SUPREME COURT OF THE UNITED STATES

2007 U.S. LEXIS 4745

November 28, 2006, Argued
April 30, 2007, Decided

NOTICE: [*1] The LEXIS pagination of this document is subject to change pending release of the final published version.

PRIOR HISTORY: ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT. Teleflex, Inc. v. KSR Int'l Co., 119 Fed. Appx. 282, 2005 U.S. App. LEXIS 176 (Fed. Cir., 2005)

DISPOSITION: Reversed and remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Respondent, licensees of a patent, alleged that petitioner, a competitor, infringed the licensees' patent for an accelerator pedal assembly for vehicles, but the competitor asserted that the patent claim in dispute was invalid as obvious under 35 U.S.C.S. § 103. Upon the grant of a writ of certiorari, the competitor appealed the judgment of the U.S. Court of Appeals for the Federal Circuit which reversed a summary judgment of patent invalidity.

OVERVIEW: To satisfy customer needs, the competitor modified its design for an adjustable pedal system for vehicles with cable-actuated throttles by adding a modular sensor to make the system compatible with vehicles using computer-controlled throttles. The licensees contended that the competitor infringed the patent claim of a position-adjustable pedal assembly with an electronic pedal position sensor attached a fixed pivot point. The U.S. Supreme Court unanimously held that the patent claim

was invalid as obvious since mounting an available sensor on a fixed pivot point of the competitor's pedal was a design step well within the grasp of a person of ordinary skill in the relevant art, and the benefit of doing so was obvious. The marketplace created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. Further, the problem to be solved by the patent claim did not limit its application as prior art, the competitor's showing that it was obvious to try a combination of elements sufficiently supported the finding of obviousness, and the claim was the result of ordinary skill and common sense rather than innovation.

OUTCOME: The judgment reversing the summary judgment of invalidity was reversed, and the case was remanded for further proceedings.

CORE TERMS: pedal, patent, sensor, skill, adjustable, pivot, electronic, obviousness, subject matter, teaching, assembly, throttle, taught, mechanical, solve, designer, invention, summary judgment, computer-controlled, combining, motivation, combine, engine, declaration, driver, modular, rigid, adjusted, inventor, predictable

LexisNexis(R) Headnotes

Patent Law > Nonobviousness > General Overview

[HN1] 35 U.S.C.S. § 103 forbids issuance of a patent when the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patent Law > Nonobviousness > Elements & Tests > Prior Art

Patent Law > Nonobviousness > Elements & Tests > Secondary Considerations

[HN2] Under 35 U.S.C.S. § 103, the scope and content of prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption

[HN3] By direction of 35 U.S.C.S. § 282, an issued patent is presumed valid.

Patent Law > Nonobviousness > Elements & Tests > Predictability

[HN4] A patent for a combination which only unites old elements with no change in their respective functions obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men. This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

Patent Law > Nonobviousness > Elements & Tests > Predictability

[HN5] When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, 35 U.S.C.S. § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its

actual application is beyond his or her skill. A court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Patent Law > Nonobviousness > Elements & Tests > General Overview

[HN6] Rejection of a patent on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support a legal conclusion of obviousness. However, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Patent Law > Nonobviousness > Elements & Tests > Prior Art

[HN7] A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Patent Law > Nonobviousness > Elements & Tests > Secondary Considerations

[HN8] The obviousness analysis in the patent context cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by over-emphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

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Patent Law > Nonobviousness > Elements & Tests > Manner of Conception***Patent Law > Nonobviousness > Elements & Tests > Predictability***

[HN9] In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under 35 U.S.C.S. § 103. One of the ways in which a patent's subject matter can be proved obvious is by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard

[HN10] A problem motivating a patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art.

Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard

[HN11] When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under 35 U.S.C.S. § 103.

Patent Law > Nonobviousness > Elements & Tests > Hindsight

[HN12] In a patent obviousness case, a factfinder must be aware of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under U.S. Supreme Court case law nor consistent with it.

Patent Law > Infringement Actions > Summary Judgment > General Overview***Patent Law > Nonobviousness > Elements & Tests > General Overview******Patent Law > Nonobviousness > Evidence & Procedure > Fact & Law Issues***

[HN13] In considering summary judgment on a question of patent obviousness, a district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. Where the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate.

Constitutional Law > Congressional Duties & Powers > Copyright & Patent Clause***Patent Law > Nonobviousness > Elements & Tests > General Overview***

[HN14] As progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. U.S. Const. art. I, § 8, cl. 8. These premises lead to the bar on patents claiming obvious subject matter established by case law and codified in 35 U.S.C.S. § 103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.

SYLLABUS: To control a conventional automobile's speed, the driver depresses or releases the gas pedal, which interacts with the throttle via a cable or other mechanical link. Because the pedal's position in the footwell normally cannot be adjusted, a driver wishing to be closer or farther from it must either reposition himself in the seat or move the seat, both of which can be imperfect solutions for smaller drivers in cars with deep footwells. This prompted inventors to design and patent pedals that could be adjusted to change their locations. The Asano patent reveals a support structure whereby, when the pedal location is [*2] adjusted, one of the pedal's pivot points stays fixed. Asano is also designed so that the force necessary to depress the pedal is the same regardless of location adjustments. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

In newer cars, computer-controlled throttles do not operate through force transferred from the pedal by a mechanical link, but open and close valves in response to electronic signals. For the computer to know what is happening with the pedal, an electronic sensor must translate the mechanical operation into digital data. Inventors had obtained a number of patents for such sensors. The so-called '936 patent taught that it was preferable to detect the pedal's position in the pedal mechanism, not in the engine, so the patent disclosed a pedal with an elec-

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tronic sensor on a pivot point in the pedal assembly. The Smith patent taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. Inventors had also patented self-contained modular sensors, which can be [*3] taken off the shelf and attached to any mechanical pedal to allow it to function with a computer-controlled throttle. The '068 patent disclosed one such sensor. Chevrolet also manufactured trucks using modular sensors attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates. Other patents disclose electronic sensors attached to adjustable pedal assemblies. For example, the Rixon patent locates the sensor in the pedal footpad, but is known for wire chafing.

After petitioner KSR developed an adjustable pedal system for cars with cable-actuated throttles and obtained its '976 patent for the design, General Motors Corporation (GMC) chose KSR to supply adjustable pedal systems for trucks using computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR added a modular sensor to its design. Respondents (Teleflex) hold the exclusive license for the Engelgau patent, claim 4 of which discloses a position-adjustable pedal assembly with an electronic pedal position sensor attached a fixed pivot point. Despite having denied a similar, broader claim, the U.S. Patent and Trademark Office (PTO) had allowed [*4] claim 4 because it included the limitation of a fixed pivot position, which distinguished the design from Redding's. Asano was neither included among the Engelgau patent's prior art references nor mentioned in the patent's prosecution, and the PTO did not have before it an adjustable pedal with a fixed pivot point. After learning of KSR's design for GMC, Teleflex sued for infringement, asserting that KSR's pedal system infringed the Engelgau patent's claim 4. KSR countered that claim 4 was invalid under § 103 of the Patent Act, which forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art."

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545, set out an objective analysis for applying § 103: "The scope and content of the prior art are . . . determined; differences between the prior art and the claims at issue are . . . ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness [*5] of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light

to the circumstances surrounding the origin of the subject matter sought to be patented." While the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry. However, seeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a "teaching, suggestion, or motivation" (TSM) test, under which a patent claim is only proved obvious if the prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings.

The District Court granted KSR summary judgment. After reviewing pedal design history, the Engelgau patent's scope, and the relevant prior art, the court considered claim 4's validity, applying *Graham's* framework to determine whether under summary-judgment standards KSR had demonstrated that claim 4 was obvious. The court found "little difference" between the prior art's teachings and claim 4: [*6] Asano taught everything contained in the claim except using a sensor to detect the pedal's position and transmit it to a computer controlling the throttle. That additional aspect was revealed in, e.g., the '068 patent and Chevrolet's sensors. The court then held that KSR satisfied the TSM test, reasoning (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to Rixon's chafing problems by positioning the sensor on the pedal's fixed structure, which could lead to the combination of a pedal like Asano with a pedal position sensor.

Reversing, the Federal Circuit ruled the District Court had not applied the TSM test strictly enough, having failed to make findings as to the specific understanding or principle within a skilled artisan's knowledge that would have motivated one with no knowledge of the invention to attach an electronic control to the Asano assembly's support bracket. The Court of Appeals held that the District Court's recourse to the nature of the problem to be solved was insufficient because, unless the prior art references [*7] addressed the precise problem that the patentee was trying to solve, the problem would not motivate an inventor to look at those references. The appeals court found that the Asano pedal was designed to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted, whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. The Rixon pedal, said the court, suffered from chafing but was not designed to solve that problem and taught nothing helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not necessarily go to the issue of motivation to attach the electronic control on the pedal assembly's support bracket. So

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interpreted, the court held, the patents would not have led a person of ordinary skill to put a sensor on an Asano-like pedal. That it might have been obvious to try that combination was likewise irrelevant. Finally, the court held that genuine issues of material fact precluded summary judgment.

Held: The Federal Circuit addressed the obviousness question in a narrow, rigid manner that is inconsistent with § 103 and this Court's precedents. KSR provided convincing [*8] evidence that mounting an available sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art and that the benefit of doing so would be obvious. Its arguments, and the record, demonstrate that the Engelgau patent's claim 4 is obvious. Pp. 11-24.

1. *Graham* provided an expansive and flexible approach to the obviousness question that is inconsistent with the way the Federal Circuit applied its TSM test here. Neither § 103's enactment nor *Graham's* analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. See *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 71 S. Ct. 127, 95 L. Ed. 162, 1951 Dec. Comm'r Pat. 572. Such a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. See, e.g., *United States v. Adams*, 383 U.S. 39, 50-52, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293. When a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or in another. If a person [*9] of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, § 103 likely bars its patentability. Moreover, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions. Following these principles may be difficult if the claimed subject matter involves more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To

facilitate review, this analysis should [*10] be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ. Pp. 11-14.

(b) The TSM test captures a helpful insight: A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. Although common sense directs caution as to a patent application claiming as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known. Helpful insights, however, need not become rigid and mandatory formulas. If it is so applied, the TSM test is incompatible with this Court's precedents. The diversity of inventive pursuits and of modern technology counsels against confining the obviousness analysis [*11] by a formalistic conception of the words teaching, suggestion, and motivation, or by over-emphasizing the importance of published articles and the explicit content of issued patents. In many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, for patents combining previously known elements, deprive prior inventions of their value or utility. Since the TSM test was devised, the Federal Circuit doubtless has applied it in accord with these principles in many cases. There is no necessary inconsistency between the test and the *Graham* analysis. But a court errs where, as here, it transforms general principle into a rigid rule limiting the obviousness inquiry. Pp. 14-15.

(c) The flaws in the Federal Circuit's analysis relate mostly to its narrow conception of the obviousness inquiry consequent in its application of the TSM test. The Circuit first erred in holding that courts and patent examiners should look only to the problem the patentee was trying [*12] to solve. Under the correct analysis, any need or problem known in the field and addressed by the patent can provide a reason for combining the elements in the manner claimed. Second, the appeals court erred in assuming that a person of ordinary skill in the art attempting to solve a problem will be led only to those prior art elements designed to solve the same problem. The court wrongly concluded that because Asano's primary purpose

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was solving the constant ratio problem, an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. It is common sense that familiar items may have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, it provided an obvious example of an adjustable pedal with a fixed pivot point, and the prior art was replete with patents indicating that such a point was an ideal mount for a sensor. Third, the court erred in concluding that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. [*13] When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. Finally, the court drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. Rigid preventative rules that deny recourse to common sense are neither necessary under, nor consistent with, this Court's case law. Pp. 15-18.

2. Application of the foregoing standards demonstrates that claim 4 is obvious. Pp. 18-23.

(a) The Court rejects Teleflex's argument that the Asano pivot mechanism's design prevents its combination with a sensor in the manner claim 4 describes. This argument was not raised before the District Court, and it is unclear whether it was raised before the Federal Circuit. Given the significance of the District Court's finding that combining Asano with a pivot-mounted pedal position sensor fell within claim 4's scope, it is apparent that Teleflex would [*14] have made clearer challenges if it intended to preserve this claim. Its failure to clearly raise the argument, and the appeals court's silence on the issue, lead this Court to accept the District Court's conclusion. Pp. 18-20.

(b) The District Court correctly concluded that when Engelgau designed the claim 4 subject matter, it was obvious to a person of ordinary skill in the art to combine Asano with a pivot-mounted pedal position sensor. There then was a marketplace creating a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The Federal Circuit considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet trucks and disclosed in the '068 patent. The proper question was whether a pedal designer of ordinary skill in the art, facing

the wide range of needs created by developments in the field, would have seen an obvious benefit to upgrading Asano with a sensor. For such a designer starting with Asano, the question was where to attach the sensor. The '936 patent taught [*15] the utility of putting the sensor on the pedal device. Smith, in turn, explained not to put the sensor on the pedal footpad, but instead on the structure. And from Rixon's known wire-chafing problems, and Smith's teaching that the pedal assemblies must not precipitate any motion in the connecting wires, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious such point is a pivot point. The designer, accordingly, would follow Smith in mounting the sensor there. Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Teleflex has not shown anything in the prior art that taught away from the use of Asano, nor any secondary factors to dislodge the determination that claim 4 is obvious. Pp. 20-23.

3. The Court disagrees with the Federal Circuit's holding that genuine issues of material fact precluded summary judgment. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17, 86 S. Ct. 684, 15 L. Ed. 2d 545. Where, as here, the [*16] prior art's content, the patent claim's scope, and the level of ordinary skill in the art are not in material dispute and the claim's obviousness is apparent, summary judgment is appropriate. P. 23.

119 Fed. Appx. 282, reversed and remanded.

JUDGES: KENNEDY, J., delivered the opinion for a unanimous Court.

OPINION BY: KENNEDY

OPINION:

JUSTICE KENNEDY delivered the opinion of the Court.

Teleflex Incorporated and its subsidiary Technology Holding Company -- both referred to here as Teleflex -- sued KSR International Company for patent infringement. The patent at issue, *United States Patent No. 6,237,565 B1*, is entitled "Adjustable Pedal Assembly With Electronic Throttle Control." Supplemental App. 1. The patentee is Steven J. Engelgau, and the patent is referred to as "the Engelgau patent." Teleflex holds the exclusive license to the patent.

Claim 4 of the Engelgau patent describes a mechanism for combining an electronic sensor with an adjust-

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able automobile pedal so the pedal's position can be transmitted to a computer that controls the throttle in the vehicle's engine. When Teleflex accused KSR of infringing the Engelgau patent by adding an electronic sensor to one of KSR's previously [*17] designed pedals, KSR countered that claim 4 was invalid under the Patent Act, 35 U.S.C. § 103, because its subject matter was obvious.

[HN1] Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966), the Court set out a framework for applying the statutory language of § 103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*, 52 U.S. 248, 11 How. 248, 13 L. Ed. 683 (1851), and its progeny. See 383 U.S. at 15-17, 86 S. Ct. 684, 15 L. Ed. 2d 545. The analysis is objective:

[HN2] "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations [*18] as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Id.* at 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545.

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

Seeking to resolve the question of obviousness with more uniformity and consistency, the Court of Appeals for the Federal Circuit has employed an approach referred to by the parties as the "teaching, suggestion, or motivation" test (TSM test), under which a patent claim is only proved obvious if "some motivation or suggestion to combine the prior art teachings" can be found in the prior art, the nature of the problem, or the knowledge of a

person having ordinary skill in the art. See, e.g., *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323-1324 (CA Fed. 1999). KSR challenges that test, or at least its application in this case. See 119 Fed. Appx. 282, 286-290 (CA Fed. 2005). [*19] Because the Court of Appeals addressed the question of obviousness in a manner contrary to § 103 and our precedents, we granted certiorari, 547 U.S. , 126 S. Ct. 2965, 165 L. Ed. 2d 949 (2006). We now reverse.

I

A

In car engines without computer-controlled throttles, the accelerator pedal interacts with the throttle via cable or other mechanical link. The pedal arm acts as a lever rotating around a pivot point. In a cable-actuated throttle control the rotation caused by pushing down the pedal pulls a cable, which in turn pulls open valves in the carburetor or fuel injection unit. The wider the valves open, the more fuel and air are released, causing combustion to increase and the car to accelerate. When the driver takes his foot off the pedal, the opposite occurs as the cable is released and the valves slide closed.

In the 1990's it became more common to install computers in cars to control engine operation. Computer-controlled throttles open and close valves in response to electronic signals, not through force transferred from the pedal by a mechanical link. Constant, delicate adjustments of air and fuel mixture are possible. The computer's rapid processing of factors beyond the pedal's position improves [*20] fuel efficiency and engine performance.

For a computer-controlled throttle to respond to a driver's operation of the car, the computer must know what is happening with the pedal. A cable or mechanical link does not suffice for this purpose; at some point, an electronic sensor is necessary to translate the mechanical operation into digital data the computer can understand.

Before discussing sensors further we turn to the mechanical design of the pedal itself. In the traditional design a pedal can be pushed down or released but cannot have its position in the footwell adjusted by sliding the pedal forward or back. As a result, a driver who wishes to be closer or farther from the pedal must either reposition himself in the driver's seat or move the seat in some way. In cars with deep footwells these are imperfect solutions for drivers of smaller stature. To solve the problem, inventors, beginning in the 1970's, designed pedals that could be adjusted to change their location in the footwell. Important for this case are two adjustable pedals disclosed in U.S. Patent Nos. 5,010,782 (filed July 28, 1989) (Asano) and 5,460,061 (filed Sept. 17, 1993) (Redding). The Asano patent reveals a [*21] support structure that

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houses the pedal so that even when the pedal location is adjusted relative to the driver, one of the pedal's pivot points stays fixed. The pedal is also designed so that the force necessary to push the pedal down is the same regardless of adjustments to its location. The Redding patent reveals a different, sliding mechanism where both the pedal and the pivot point are adjusted.

We return to sensors. Well before Engelgau applied for his challenged patent, some inventors had obtained patents involving electronic pedal sensors for computer-controlled throttles. These inventions, such as the device disclosed in U.S. Patent No. 5,241,936 (filed Sept. 9, 1991) ('936), taught that it was preferable to detect the pedal's position in the pedal assembly, not in the engine. The '936 patent disclosed a pedal with an electronic sensor on a pivot point in the pedal assembly. U.S. Patent No. 5,063,811 (filed July 9, 1990) (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, and to avoid grime and damage from the driver's foot, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's [*22] footpad.

In addition to patents for pedals with integrated sensors inventors obtained patents for self-contained modular sensors. A modular sensor is designed independently of a given pedal so that it can be taken off the shelf and attached to mechanical pedals of various sorts, enabling the pedals to be used in automobiles with computer-controlled throttles. One such sensor was disclosed in U.S. Patent No. 5,385,068 (filed Dec. 18, 1992) ('068). In 1994, Chevrolet manufactured a line of trucks using modular sensors "attached to the pedal support bracket, adjacent to the pedal and engaged with the pivot shaft about which the pedal rotates in operation." 298 F. Supp. 2d 581, 589 (ED Mich. 2003).

The prior art contained patents involving the placement of sensors on adjustable pedals as well. For example, U.S. Patent No. 5,819,593 (filed Aug. 17, 1995) (Rixon) discloses an adjustable pedal assembly with an electronic sensor for detecting the pedal's position. In the Rixon pedal the sensor is located in the pedal footpad. The Rixon pedal was known to suffer from wire chafing when the pedal was depressed and released.

This short account of pedal and sensor technology leads [*23] to the instant case.

B

KSR, a Canadian company, manufactures and supplies auto parts, including pedal systems. Ford Motor Company hired KSR in 1998 to supply an adjustable pedal system for various lines of automobiles with cable-actuated throttle controls. KSR developed an adjustable mechanical pedal for Ford and obtained U.S. Patent

No. 6,151,976 (filed July 16, 1999) ('976) for the design. In 2000, KSR was chosen by General Motors Corporation (GMC or GM) to supply adjustable pedal systems for Chevrolet and GMC light trucks that used engines with computer-controlled throttles. To make the '976 pedal compatible with the trucks, KSR merely took that design and added a modular sensor.

Teleflex is a rival to KSR in the design and manufacture of adjustable pedals. As noted, it is the exclusive licensee of the Engelgau patent. Engelgau filed the patent application on August 22, 2000 as a continuation of a previous application for U.S. Patent No. 6,109,241, which was filed on January 26, 1999. He has sworn he invented the patent's subject matter on February 14, 1998. The Engelgau patent discloses an adjustable electronic pedal described in the specification as a "simplified vehicle control [*24] pedal assembly that is less expensive, and which uses fewer parts and is easier to package within the vehicle." Engelgau, col. 2, lines 2-5, Supplemental App. 6. Claim 4 of the patent, at issue here, describes:

"A vehicle control pedal apparatus comprising:

a support adapted to be mounted to a vehicle structure;

an adjustable pedal assembly having a pedal arm moveable in fore and aft directions with respect to said support;

a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and

an electronic control attached to said support for controlling a vehicle system;

said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot." *Id.*, col. 6, lines 17-36, Supplemental App. 8 (diagram numbers omitted).

We agree with the District Court that the claim discloses "a position-adjustable pedal [*25] assembly with an electronic pedal position sensor attached to the support member of the pedal assembly. Attaching the sensor to the

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support member allows the sensor to remain in a fixed position while the driver adjusts the pedal." 298 F. Supp. 2d, at 586-587.

Before issuing the Engelgau patent the U.S. Patent and Trademark Office (PTO) rejected one of the patent claims that was similar to, but broader than, the present claim 4. The claim did not include the requirement that the sensor be placed on a fixed pivot point. The PTO concluded the claim was an obvious combination of the prior art disclosed in Redding and Smith, explaining:

"Since the prior art references are from the field of endeavor, the purpose disclosed . . . would have been recognized in the pertinent art of Redding. Therefore it would have been obvious . . . to provide the device of Redding with the . . . means attached to a support member as taught by Smith." Id., at 595.

In other words Redding provided an example of an adjustable pedal and Smith explained how to mount a sensor on a pedal's support structure, and the rejected patent claim merely put these two teachings together. [*26]

Although the broader claim was rejected, claim 4 was later allowed because it included the limitation of a fixed pivot point, which distinguished the design from Redding's. *Ibid.* Engelgau had not included Asano among the prior art references, and Asano was not mentioned in the patent's prosecution. Thus, the PTO did not have before it an adjustable pedal with a fixed pivot point. The patent issued on May 29, 2001 and was assigned to Teleflex.

Upon learning of KSR's design for GM, Teleflex sent a warning letter informing KSR that its proposal would violate the Engelgau patent. "Teleflex believes that any supplier of a product that combines an adjustable pedal with an electronic throttle control necessarily employs technology covered by one or more" of Teleflex's patents. Id., at 585. KSR refused to enter a royalty arrangement with Teleflex; so Teleflex sued for infringement, asserting KSR's pedal infringed the Engelgau patent and two other patents. *Ibid.* Teleflex later abandoned its claims regarding the other patents and dedicated the patents to the public. The remaining contention was that KSR's pedal system for GM infringed claim 4 of the Engelgau patent. [*27] Teleflex has not argued that the other three claims of the patent are infringed by KSR's pedal, nor has Teleflex argued that the mechanical adjustable pedal designed by KSR for Ford infringed any of its patents.

C

The District Court granted summary judgment in KSR's favor. After reviewing the pertinent history of pedal design, the scope of the Engelgau patent, and the relevant prior art, the court considered the validity of the contested claim. [HN3] By direction of 35 U.S.C. § 282, an issued patent is presumed valid. The District Court applied *Graham's* framework to determine whether under summary-judgment standards KSR had overcome the presumption and demonstrated that claim 4 was obvious in light of the prior art in existence when the claimed subject matter was invented. See § 102(a).

The District Court determined, in light of the expert testimony and the parties' stipulations, that the level of ordinary skill in pedal design was "an undergraduate degree in mechanical engineering (or an equivalent amount of industry experience) [and] familiarity with pedal control systems for vehicles." 298 F. Supp. 2d, at 590. The court then set forth the [*28] relevant prior art, including the patents and pedal designs described above.

Following *Graham's* direction, the court compared the teachings of the prior art to the claims of Engelgau. It found "little difference." 298 F. Supp. 2d, at 590. Asano taught everything contained in claim 4 except the use of a sensor to detect the pedal's position and transmit it to the computer controlling the throttle. That additional aspect was revealed in sources such as the '068 patent and the sensors used by Chevrolet.

Under the controlling cases from the Court of Appeals for the Federal Circuit, however, the District Court was not permitted to stop there. The court was required also to apply the TSM test. The District Court held KSR had satisfied the test. It reasoned (1) the state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals, (2) Rixon provided the basis for these developments, and (3) Smith taught a solution to the wire chafing problems in Rixon, namely locating the sensor on the fixed structure of the pedal. This could lead to the combination of Asano, or a pedal like it, with a pedal position sensor.

The conclusion that the [*29] Engelgau design was obvious was supported, in the District Court's view, by the PTO's rejection of the broader version of claim 4. Had Engelgau included Asano in his patent application, it reasoned, the PTO would have found claim 4 to be an obvious combination of Asano and Smith, as it had found the broader version an obvious combination of Redding and Smith. As a final matter, the District Court held that the secondary factor of Teleflex's commercial success with pedals based on Engelgau's design did not alter its conclusion. The District Court granted summary judgment for KSR.

With principal reliance on the TSM test, the Court of Appeals reversed. It ruled the District Court had not been

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strict enough in applying the test, having failed to make "findings as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention" . . . to attach an electronic control to the support bracket of the Asano assembly." 119 Fed. Appx., at 288 (brackets in original) (quoting *In re Kotzab*, 217 F.3d 1365, 1371 (CA Fed. 2000)). The Court of Appeals held that the District Court was [*30] incorrect that the nature of the problem to be solved satisfied this requirement because unless the "prior art references addressed the precise problem that the patentee was trying to solve," the problem would not motivate an inventor to look at those references. 119 Fed. Appx., at 288.

Here, the Court of Appeals found, the Asano pedal was designed to solve the "constant ratio problem" -- that is, to ensure that the force required to depress the pedal is the same no matter how the pedal is adjusted -- whereas Engelgau sought to provide a simpler, smaller, cheaper adjustable electronic pedal. *Ibid.* As for Rixon, the court explained, that pedal suffered from the problem of wire chafing but was not designed to solve it. In the court's view Rixon did not teach anything helpful to Engelgau's purpose. Smith, in turn, did not relate to adjustable pedals and did not "necessarily go to the issue of motivation to attach the electronic control on the support bracket of the pedal assembly." *Ibid.* When the patents were interpreted in this way, the Court of Appeals held, they would not have led a person of ordinary skill to put a sensor on the sort of pedal described in Asano. [*31]

That it might have been obvious to try the combination of Asano and a sensor was likewise irrelevant, in the court's view, because " "obvious to try" has long been held not to constitute obviousness." *Id.*, at 289 (quoting *In re Deuel*, 51 F.3d 1552, 1559 (CA Fed. 1995)).

The Court of Appeals also faulted the District Court's consideration of the PTO's rejection of the broader version of claim 4. The District Court's role, the Court of Appeals explained, was not to speculate regarding what the PTO might have done had the Engelgau patent mentioned Asano. Rather, the court held, the District Court was obliged first to presume that the issued patent was valid and then to render its own independent judgment of obviousness based on a review of the prior art. The fact that the PTO had rejected the broader version of claim 4, the Court of Appeals said, had no place in that analysis.

The Court of Appeals further held that genuine issues of material fact precluded summary judgment. Teleflex had proffered statements from one expert that claim 4 "was a simple, elegant, and novel combination of features," 119 Fed. Appx., at 290, compared to Rixon, [*32] and from another expert that claim 4 was nonobvious because, unlike in Rixon, the sensor was mounted on the

support bracket rather than the pedal itself. This evidence, the court concluded, sufficed to require a trial.

II

A

We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here. To be sure, *Graham* recognized the need for "uniformity and definiteness." 383 U.S., at 18, 86 S. Ct. 684, 15 L. Ed. 2d 545. Yet the principles laid down in *Graham* reaffirmed the "functional approach" of *Hotchkiss*, 52 U.S. 248, 11 How. 248, 13 L. Ed. 683. See 383 U.S., at 12, 86 S. Ct. 684, 15 L. Ed. 2d 545. To this end, *Graham* set forth a broad inquiry and invited courts, where appropriate, to look at any secondary considerations that would prove instructive. *Id.*, at 17, 86 S. Ct. 684, 15 L. Ed. 2d 545.

Neither the enactment of § 103 nor the analysis in *Graham* disturbed this Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art. For over a half century, [*33] the Court has held that [HN4] a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 71 S. Ct. 127, 95 L. Ed. 162, 1951 Dec. Comm'r Pat. 572 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. Three cases decided after *Graham* illustrate the application of this doctrine.

In *United States v. Adams*, 383 U.S. 39, 40, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293 (1966), a companion case to *Graham*, the Court considered the obviousness of a "wet battery" that varied from prior designs in two ways: It contained water, rather than the acids conventionally employed in storage batteries; and its electrodes were magnesium and cuprous chloride, rather than zinc and silver chloride. The Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one [*34] element for another known in the field, the combination must do more than yield a predictable result. 383 U.S., at 50-51, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293. It nevertheless rejected the Government's claim that Adams's battery was obvious. The Court relied upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a

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successful means of combining them is more likely to be nonobvious. *Id.*, at 51-52, 86 S. Ct. 708, 15 L. Ed. 2d 572, 174 Ct. Cl. 1293. When Adams designed his battery, the prior art warned that risks were involved in using the types of electrodes he employed. The fact that the elements worked together in an unexpected and fruitful manner supported the conclusion that Adams's design was not obvious to those skilled in the art.

In *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 90 S. Ct. 305, 24 L. Ed. 2d 258 (1969), the Court elaborated on this approach. The subject matter of the patent before the Court was a device combining two pre-existing elements: a radiant-heat burner and a paving machine. The device, the Court concluded, did not create some new synergy: The radiant-heat burner functioned just as a burner was expected to function; and the paving machine did [*35] the same. The two in combination did no more than they would in separate, sequential operation. *Id.*, at 60-62, 90 S. Ct. 305, 24 L. Ed. 2d 258. In those circumstances, "while the combination of old elements performed a useful function, it added nothing to the nature and quality of the radiant-heat burner already patented," and the patent failed under § 103. *Id.*, at 62, 90 S. Ct. 305, 24 L. Ed. 2d 258 (footnote omitted).

Finally, in *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 96 S. Ct. 1532, 47 L. Ed. 2d 784 (1976), the Court derived from the precedents the conclusion that when a patent "simply arranges old elements with each performing the same function it had been known to perform" and yields no more than one would expect from such an arrangement, the combination is obvious. *Id.*, at 282, 96 S. Ct. 1532, 47 L. Ed. 2d 784.

The principles underlying these cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. [HN5] When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For [*36] the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Sakraida* and *Anderson's-Black Rock* are illustrative -- a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.

Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the

improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis [*37] should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ([HN6] "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

B

When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. See *Application of Bergel*, 292 F.2d 955, 956-957, 48 C.C.P.A. 1102, 1961 Dec. Comm'r Pat. 504 (1961). As is clear from cases such as *Adams*, [HN7] a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation [*38] the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. [HN8] The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protec-

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tion [*39] to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.

C

The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test. [HN9] In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103. One of the ways in which a patent's subject matter can be proved obvious is [*40] by noting that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims.

The first error of the Court of Appeals in this case was to foreclose this reasoning by holding that courts and patent examiners should look only to the problem the patentee was trying to solve. 119 Fed. Appx., at 288. The Court of Appeals failed to recognize that [HN10] the problem motivating the patentee may be only one of many addressed by the patent's subject matter. The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art. Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

The second error of the Court of Appeals lay in its assumption that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem. *Ibid.* The primary purpose of Asano was solving the constant ratio problem; so, the court concluded, [*41] an inventor considering how to put a sensor on an adjustable pedal would have no reason to consider putting it on the Asano pedal. *Ibid.* Common sense teaches, however, that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle. Regardless of Asano's primary purpose, the design provided an obvious example of an adjustable pedal with

a fixed pivot point; and the prior art was replete with patents indicating that a fixed pivot point was an ideal mount for a sensor. The idea that a designer hoping to make an adjustable electronic pedal would ignore Asano because Asano was designed to solve the constant ratio problem makes little sense. A person of ordinary skill is also a person of ordinary creativity, not an automaton.

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). [HN11] When there is a design need or market pressure to solve a problem [*42] and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. [HN12] A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight") (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (CA6 1964)). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

We note the [*43] Court of Appeals has since elaborated a broader conception of the TSM test than was applied in the instant matter. See, e.g., *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (2006) ("Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense"); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (2006) ("There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine . . ."). Those decisions, of course, are not now before us and do not correct the errors of law made by the Court of Appeals in this case. The extent to which they may describe an analysis more consistent with our earlier precedents and our decision here is a matter for the Court of Appeals to consider in its future cases. What we hold is that the fundamental misunderstandings identified above led the Court of Appeals

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in this case to apply a test inconsistent with our patent law decisions.

III

When we apply the standards we have [*44] explained to the instant facts, claim 4 must be found obvious. We agree with and adopt the District Court's recitation of the relevant prior art and its determination of the level of ordinary skill in the field. As did the District Court, we see little difference between the teachings of Asano and Smith and the adjustable electronic pedal disclosed in claim 4 of the Engelgau patent. A person having ordinary skill in the art could have combined Asano with a pedal position sensor in a fashion encompassed by claim 4, and would have seen the benefits of doing so.

A

Teleflex argues in passing that the Asano pedal cannot be combined with a sensor in the manner described by claim 4 because of the design of Asano's pivot mechanisms. See Brief for Respondents 48-49, and n. 17. Therefore, Teleflex reasons, even if adding a sensor to Asano was obvious, that does not establish that claim 4 encompasses obvious subject matter. This argument was not, however, raised before the District Court. There Teleflex was content to assert only that the problem motivating the invention claimed by the Engelgau patent would not lead to the solution of combining of Asano with a sensor. See Teleflex's Response [*45] to KSR's Motion for Summary Judgment of Invalidity in No. 02-74586 (ED Mich.), pp. 18-20, App. 144a-146a. It is also unclear whether the current argument was raised before the Court of Appeals, where Teleflex advanced the nonspecific, conclusory contention that combining Asano with a sensor would not satisfy the limitations of claim 4. See Brief for Plaintiffs-Appellants in No. 04-1152 (CA Fed.), pp. 42-44. Teleflex's own expert declarations, moreover, do not support the point Teleflex now raises. See Declaration of Clark J. Radcliffe, Ph.D., Supplemental App. 204-207; Declaration of Timothy L. Andresen, *id.*, at 208-210. The only statement in either declaration that might bear on the argument is found in the Radcliffe declaration:

Asano . . . and Rixon . . . are complex mechanical linkage-based devices that are expensive to produce and assemble and difficult to package. It is exactly these difficulties with prior art designs that [Engelgau] resolves. The use of an adjustable pedal with a single pivot reflecting pedal position combined with an electronic control mounted between the support and the adjustment assembly at that pivot was a simple, elegant, and novel combination

[*46] of features in the Engelgau '565 patent." *Id.*, at 206, P16.

Read in the context of the declaration as a whole this is best interpreted to mean that Asano could not be used to solve "the problem addressed by Engelgau '565[:] to provide a less expensive, more quickly assembled, and smaller package adjustable pedal assembly with electronic control." *Id.*, at 205, P10.

The District Court found that combining Asano with a pivot-mounted pedal position sensor fell within the scope of claim 4. 298 F. Supp. 2d, at 592-593. Given the significance of that finding to the District Court's judgment, it is apparent that Teleflex would have made clearer challenges to it if it intended to preserve this claim. In light of Teleflex's failure to raise the argument in a clear fashion, and the silence of the Court of Appeals on the issue, we take the District Court's conclusion on the point to be correct.

B

The District Court was correct to conclude that, as of the time Engelgau designed the subject matter in claim 4, it was obvious to a person of ordinary skill to combine Asano with a pivot-mounted pedal position sensor. There then existed a marketplace that created a strong [*47] incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance. The Court of Appeals considered the issue too narrowly by, in effect, asking whether a pedal designer writing on a blank slate would have chosen both Asano and a modular sensor similar to the ones used in the Chevrolet truckline and disclosed in the '068 patent. The District Court employed this narrow inquiry as well, though it reached the correct result nevertheless. The proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor.

In automotive design, as in many other fields, the interaction of multiple components means that changing one component often requires the others to be modified as well. Technological developments made it clear that engines using computer-controlled throttles would become standard. As a result, designers might have decided to design new pedals from scratch; but they also would have had reason to make pre-existing pedals work with the new engines. Indeed, upgrading its [*48] own pre-existing model led KSR to design the pedal now accused of infringing the Engelgau patent.

For a designer starting with Asano, the question was where to attach the sensor. The consequent legal question, then, is whether a pedal designer of ordinary skill starting

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with Asano would have found it obvious to put the sensor on a fixed pivot point. The prior art discussed above leads us to the conclusion that attaching the sensor where both KSR and Engelgau put it would have been obvious to a person of ordinary skill.

The '936 patent taught the utility of putting the sensor on the pedal device, not in the engine. Smith, in turn, explained to put the sensor not on the pedal's footpad but instead on its support structure. And from the known wire-chafing problems of Rixon, and Smith's teaching that "the pedal assemblies must not precipitate any motion in the connecting wires," Smith, col. 1, lines 35-37, Supplemental App. 274, the designer would know to place the sensor on a nonmoving part of the pedal structure. The most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position is a pivot point. The designer, accordingly, would follow Smith [*49] in mounting the sensor on a pivot, thereby designing an adjustable electronic pedal covered by claim 4.

Just as it was possible to begin with the objective to upgrade Asano to work with a computer-controlled throttle, so too was it possible to take an adjustable electronic pedal like Rixon and seek an improvement that would avoid the wire-chafing problem. Following similar steps to those just explained, a designer would learn from Smith to avoid sensor movement and would come, thereby, to Asano because Asano disclosed an adjustable pedal with a fixed pivot.

Teleflex indirectly argues that the prior art taught away from attaching a sensor to Asano because Asano in its view is bulky, complex, and expensive. The only evidence Teleflex marshals in support of this argument, however, is the Radcliffe declaration, which merely indicates that Asano would not have solved Engelgau's goal of making a small, simple, and inexpensive pedal. What the declaration does not indicate is that Asano was somehow so flawed that there was no reason to upgrade it, or pedals like it, to be compatible with modern engines. Indeed, Teleflex's own declarations refute this conclusion. Dr. Radcliffe states that [*50] Rixon suffered from the same bulk and complexity as did Asano. See *id.*, at 206. Teleflex's other expert, however, explained that Rixon was itself designed by adding a sensor to a pre-existing mechanical pedal. See *id.*, at 209. If Rixon's base pedal was not too flawed to upgrade, then Dr. Radcliffe's declaration does not show Asano was either. Teleflex may have made a plausible argument that Asano is inefficient as compared to Engelgau's preferred embodiment, but to judge Asano against Engelgau would be to engage in the very hindsight bias Teleflex rightly urges must be avoided. Accordingly, Teleflex has not shown anything in the prior art that taught away from the use of Asano.

Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious. Proper application of *Graham* and our other precedents to these facts therefore leads to the conclusion that claim 4 encompassed obvious subject matter. As a result, the claim fails to meet the requirement of § 103.

We need not reach the question whether the failure to disclose Asano during the prosecution of Engelgau voids the presumption of validity given [*51] to issued patents, for claim 4 is obvious despite the presumption. We nevertheless think it appropriate to note that the rationale underlying the presumption -- that the PTO, in its expertise, has approved the claim -- seems much diminished here.

IV

A separate ground the Court of Appeals gave for reversing the order for summary judgment was the existence of a dispute over an issue of material fact. We disagree with the Court of Appeals on this point as well. To the extent the court understood the *Graham* approach to exclude the possibility of summary judgment when an expert provides a conclusory affidavit addressing the question of obviousness, it misunderstood the role expert testimony plays in the analysis. [HN13] In considering summary judgment on that question the district court can and should take into account expert testimony, which may resolve or keep open certain questions of fact. That is not the end of the issue, however. The ultimate judgment of obviousness is a legal determination. *Graham*, 383 U.S., at 17, 86 S. Ct. 684, 15 L. Ed. 2d 545. Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and [*52] the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate. Nothing in the declarations proffered by Teleflex prevented the District Court from reaching the careful conclusions underlying its order for summary judgment in this case.

* * *

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And [HN14] as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See *U.S. Const., Art. I, § 8, cl. 8*. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss*

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and codified in § 103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose.

KSR provided convincing evidence that mounting a modular [*53] sensor on a fixed pivot point of the Asano pedal was a design step well within the grasp of a person of ordinary skill in the relevant art. Its arguments, and the record, demonstrate that claim 4 of the Engelgau patent is obvious. In rejecting the District Court's rulings, the Court of Appeals analyzed the issue in a narrow, rigid manner inconsistent with § 103 and our precedents. The judgment

of the Court of Appeals is reversed, and the case remanded for further proceedings consistent with this opinion.

It is so ordered.

REFERENCES: Go To Full Text Opinion

Go To Supreme Court Brief(s)

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EXHIBIT 15

**THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY**

EXHIBIT 16

**THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY**

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on May 14, 2007, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

BY HAND DELIVERY AND E-MAIL

Jeffrey B. Bove, Esq.
Mary W. Bourke, Esq.
Mark E. Freeman, Esq.
Jaclyn Mason, Esq.
Donna Hallowell
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
P. O. Box 2207
Wilmington, DE 19899-2207
jbove@cblh.com, mbourke@cblh.com
mfreeman@cblh.com, jmason@cblh.com
dhallowell@cblh.com; cjeffers@cblh.com;
dhammond@cblh.com; mlambert@cblh.com

BY EMAIL

Dana K. Hammond, Esq.
M. Curt Lambert, Esq.
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
Wilmington, DE 19899
jhammond@cblh.com; mlambert@cblh.com

Christopher E. Jeffers, Esq.
Connolly Bove Lodge & Hutz LLP
1990 M. Street, NW
Washington, DC 20036-3425
cjeffers@cblh.com

I hereby certify that on May 14, 2007 I have sent by E-mail and Federal Express the foregoing document to the following non-registered participants:

Bradford J. Badke, Esq.
Gabrielle Ciuffreda, Esq.
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10036-8704
bradford.badke@ropesgray.com; gabrielle.ciuffreda@ropesgray.com

/s/ Philip A. Rovner
Philip A. Rovner (#3215)
Potter Anderson & Corroon LLP
Hercules Plaza
P. O. Box 951
Wilmington, DE 19899
(302) 984-6000
provner@potteranderson.com